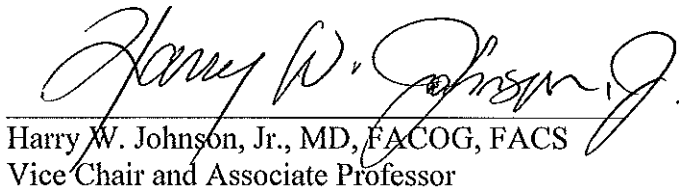
Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES**	

GENERAL EXPERT REPORT (PROLIFT/GYNEMESH PS) OF HARRY JOHNSON, JR., MD

Prepared by:



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Date: February 15, 2017

Harry Johnson, M.D.- Expert Report

Education, training and experience:

I am Board certified in OB/GYN and Female Pelvic Medicine and Reconstructive Surgery. I am a surgeon who practices in Baltimore, Maryland, at the University of Maryland Medical Center. I completed medical training at Wake Forest University, Bowman Grey School of Medicine in 1984. After obtaining a MD, I completed an internship in General Surgery in 1985 at Wake Forest University Medical Center, followed by OB/GYN residency at University of Maryland Medical Center.

I then served in the U.S. Navy Medical Corps where I held a teaching position at the National Naval Medical Center in Bethesda, MD in OB/GYN. At Bethesda, I was a teaching physician in the OB/GYN residency specializing in gynecologic surgery and urogynecology. In addition, I served in the Persian Gulf War. Upon completing military service, I joined the faculty at the University of Maryland Medical Center and completed a pelvic surgery fellowship at Greater Baltimore Medical Center. On returning to University of Maryland, I established the Division of Urogynecology and Pelvic Reconstructive Surgery. Since arriving here in 1992, my practice has been focused on urinary incontinence and pelvic organ prolapse in women.

Since 1992, I have presented invited lectures on surgical and medical management of urinary incontinence and pelvic organ prolapse. In addition, I have taught community physicians to perform surgical procedures.

I was the OB/GYN Residency Training Director from 1994 through 2005. The training program has 7 residents per year. I have trained 19 fellows in urogynecology and pelvic reconstructive surgery. Currently, I am the Associate Chairman of OB/GYN, Division Director of Urogynecology and Reconstructive Surgery, and interim Director of GYN Oncology. My academic rank is Associate Professor in OB/GYN, Associate Professor of Surgery, Division of Urology. I am actively involved in teaching of OB/GYN and Urology residents.

I perform approximately 200 procedures for the treatment of pelvic organ prolapse and/or stress urinary incontinence per year. I have performed at least 800 polypropylene midurethral slings. I have also performed hundreds of prolapse procedures utilizing Prolift (Anterior, Posterior and Total), as well as Prolene Soft. I work in a tertiary medical center and am a regional resource center for evaluation and treatment of complications related to incontinence and prolapse surgery. I currently use TVT-O and TVT- Exact. TVT-Exact is identical to TVT classic except with slightly smaller needles. I currently use Coloplast for prolapse repairs.

I am a co-principle investigator and founding member of the Urinary Incontinence Treatment Network (UITN) which was established by the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) in 2000. The UITN consists of 9 major medical centers and one data collection center:

- University of Alabama at Birmingham, Birmingham, Alabama
- Department of Veterans Affairs, Birmingham, Alabama

- Loyola University Stritch School of Medicine, Chicago, Illinois
- University of Texas Southwestern, Dallas, Texas
- New England Research Institutes, Wate1town, Massachusetts
- Duquesne University, Pittsburgh, Pennsylvania
- Kaiser Permanente, San Diego, California
- William Beaumont Hospital, Royal Oak, Michigan
- University of Texas Health Sciences Center, San Antonio, Texas
- University of Maryland, Baltimore, Maryland

The UITN Network conducted large, prospective, randomized, surgical trials of the most common treatments for women with urinary incontinence from 2000-2010. We performed trials of fascial slings, Burch colposuspension and midurethral synthetic slings, primarily TVT, TVT-0 and Monarch slings under a Grant from the National Institute of Health (NIH).

My opinions are held to a reasonable degree of medical and scientific certainty. My opinions are based on my education, training, knowledge, personal and clinical experience, publications, lectures, teaching, review of the literature, and interactions with colleagues.

A list of materials I have reviewed and which I may use at trial is attached as **Exhibit A**. The materials identified in Exhibit A are in addition to those set forth in my CV, which is attached as **Exhibit B**. A list of my prior testimony is attached as **Exhibit C**. Specifically, in the past four years I have given testimony in the following cases:

- 11/6/13, Richardson v Miller deposition
- 8/28/13, Woods v Cossell deposition
- 3/20/13, Rodriguez v Rao deposition
- 2014, Fleming v. Pleeter
- 2014, Stidham
- 2015, Streaker v. Boushehri
- 2015, Ehrsam v. Hopkins
- 2015, Harris v. McMillan
- 2016, Powers v. Harrison
- 4/29/16, Riggs v. Ethicon
- 6/21/16, Bihlmeyer v. Ethicon
- 7/14/16, General deposition (Consolidated Litigation)
- 7/15/16, Bennett v. Ethicon
- 7/13/16, Garcia v. Ethicon
- 7/13/16, Martinez v. Ethicon
- 7/15/16, Mullens v. Ethicon
- 7/13/16, Tomblin v. Ethicon
- 7/14/16, Webb v. Ethicon
- 9/1/16, Onal v. University of Maryland
- 11/18/16, Chase v. Ethicon
- 2/9/17, Powers v. Harrison

My rates for expert work are:

- $400.00/hour: telephone consultation, record review, literature search, deposition review
- $600.00/hour: deposition meetings, deposition testimony, pre-trial meetings
- $2500.00 half-day (plus expenses): court testimony
- $5000.00 entire day (plus expenses: court testimony

Summary of Opinions:

- Prolift, made with Gynemesh PS, is an effective option for the treatment of pelvic organ prolapse. Prolift provides superior anatomic cure rates and quality of life improvement compared to native tissue repairs, which are known to have a high failure rate.

- Prolift is a safe option for the treatment of pelvic organ prolapse. Gynemesh PS has been studied more than any other medical device for the surgical treatment of pelvic organ prolapse, and the clinical data do not demonstrate a statistically significant higher rate of complications with Prolift when compared to native tissue repair.

- Prolift utilizing Gynemesh PS is not defective in its design, and there is no reliable data or literature demonstrating that the alternative designs proposed by some of Plaintiffs' experts are safer and more effective in the treatment of pelvic organ prolapse.

- The risks associated with Prolift and Gynemesh PS are nearly identical to the risks associated with native tissue repair. Pelvic floor surgeons should be aware of the risks associated with surgeries to repair prolapse, with or without mesh. The only complication associated with Prolift/Gynemesh PS that is unique to the use of mesh is mesh erosion (also referred to as exposure or extrusion), which is a known risk associated with implanting a foreign body and is known to occur with polypropylene sutures as well as biologic implants. Additionally, the Instructions for Use accompanying Gynemesh PS and the Prolift device clearly warn of the risk of exposure.

I. BACKGROUND

A. Pelvic Organ Prolapse

Pelvic organ prolapse ("POP") occurs when one or more of the pelvic organs (such as the bladder, bowel or uterus) drops from its normal anatomical position, protruding into or beyond the vagina, due to weakening of the pelvic floor tissues that normally support these organs. Pelvic organ prolapse is a common condition affecting millions of women, and its prevalence increases with age, occurring in 50% of all women over the age of 50. The lifetime incidence of POP reportedly ranges from 30-50% (da Silveira 2014).

Risk factors include aging, pregnancy, childbirth, obesity, actions or conditions causing chronically raised intra-abdominal pressure (such as heavy lifting, chronic cough/COPD, chronic constipation), tissue abnormalities (both congenital and acquired), denervation or weakness of the pelvic floor, hysterectomy, and menopause. Symptomatic POP is known to significantly impair a woman's daily functioning and adversely affect a woman's quality of life and wellbeing—physically, emotionally, and psychologically (Subak 2001; Abdel-Fattah 2011). Symptoms include pelvic pain, discomfort, or heaviness; the sensation of a bulge or protrusion from the vagina; back pain; and symptoms of bladder, bowel and/or sexual dysfunction (Maher 2013). Many women with POP (approximately 55% of women with Stage II or higher) also have stress urinary incontinence ("SUI") (Maher 2013). Additionally, occult or "masked" SUI is a common

occurrence following reduction of pelvic organ prolapse, and has been reported in up to 65% of women who have undergone surgical treatment for POP (Reena 2007). In other words, many women have both POP and SUI, but the SUI is asymptomatic until after the correction of the prolapse, which was preventing the SUI symptoms that she would have been experiencing but for the prolapse.

B. Treatment Options

1. Nonsurgical

There are numerous surgical and non-surgical options for the treatment of POP depending upon the degree of prolapse and severity of symptoms. Non-surgical options are appropriate for asymptomatic or low grade prolapse and include pelvic floor exercises and the use of a pessary. Pelvic floor exercises (e.g., Kegels) are designed to strengthen the muscles supporting the pelvic organs. A pessary is a removable device that provides support for the pelvic organs and is inserted into the vagina. However, the pessary can cause pain or discomfort and must be regularly removed for cleaning and prior to intercourse, which can be inconvenient for the patient. The use of a pessary also requires frequent position check-ups and can cause vaginal bleeding, discharge and odor. For these reasons, a pessary is frequently not considered to be a satisfactory treatment option, and surgical intervention is desired by the patient.

2. Surgical

There is a 7% lifetime risk of surgery for prolapse (Olsen, et al. Obst & Gynec 1997;89:501). Of those patients, 29% will require reoperation. The lifetime risk of a single operation for POP/UI increases with age, 0.9% ages 30-39 to 11.1% at ages 70-79 (Olsen). There are numerous surgical options for the treatment of POP, and the best option for any given patient is dependent upon a number of factors, including: the nature and severity of the prolapse and its associated symptoms; the patient's general health and wellbeing, including social history and comorbidities; patient preference; and the preference, skill and training of the surgeon. The goal of surgery is to restore normal pelvic anatomy and support, as well as normal bladder, bowel and/or sexual function.

The surgical alternatives include procedures performed abdominally or vaginally, with or without the use of synthetic or biologic grafts. Surgical procedures are designed to correct specific compartment defects. Surgical risks are present for all vaginal reconstructive surgery. These include: bleeding/hemorrhage, cystotomy, proctotomy, fistula, vaginal/pelvic infection, voiding difficulty/dysfunction, urinary tract infection, ureteral injury/obstruction, vaginal stenosis and dyspareunia. A brief description of some of the surgical options, as well as the associated success and complication rates, follows.

McCall Culdoplasty:

Culdo sac is plicated between the uterosacral ligaments. Vaginal apex is attached to the plicated ligaments.

Success rate 82-93%	(Sze and Karran 1997)
Success rate 82%	(Webb, et al 1998)

Illio Coccygeus Fascia Suspension:

Used when vagina is not long enough to reach sacrospinous ligament making it unsafe or impossible to perform. Attach vaginal to fascia below ischial spine. Success rate equal to sacrospinous ligament suspension. (Maher, et al).

Sacrospinous Ligament Suspension (SSLS):

Attached vaginal apex to sacrospinous ligament which is located in coccygeus muscle. Most commonly fails in the anterior compartment.

Failure rate (Paraisio) or recurrence rate:

37% Anterior compartment

13% Posterior compartment

8% Apical

Complications specific to SSLS:

Pudendal nerve and artery injury

Sciatic nerve injury

Gluteal vessels

Hypogastric venous plexus

Moderate to severe buttock pain

Vaginal stenosis

Dyspareunia

Uterosacral Ligament Colpopexy:

Performed by attaching the vaginal apex to the uterosacral ligament bilaterally at the level of the ischial spine. Specific complications include ureteral injury rate 2-4% with range of 0-11%. Nerve pain from S 2-4 sacral nerve roots.

Outcome in systematic review by Marguiles, et al 2016, showed pooled role for successful outcome of:

Anterior compartment 81.2%

Apical compartment 98.3%

Posterior compartment 87.4%

Anterior Colporrhaphy:

Used to treat anterior wall prolapse. Performed by dissecting the vagina away from the bladder and placating the pubovesical fascia. Success rates have been poor, ranging from 30%-90%.

Complications include: Excessive blood loss, hematoma, injury to urethra, bladder and ureter, fistula, intravesicle or intraurethral suture placement, de novo stress incontinence, voiding dysfunction, UTI, and infection.

Paravaginal repair:

Used to treat anterior wall prolapse. Vaginal or abdominal approach. Vagina is attached laterally to arcus tendentious fascia pelvis – bilaterally.

Outcomes –

Vaginal success 67-100%

Open abdominal 75-97%

Posterior Colporrhaphy:

Used to treat posterior compartment defect midline plication of rectovaginal fascia or defect directed repair of rectovaginal fascia.

Anatomic success rate 83% (76-96%)

Postoperative dyspareunia 18% (5-45%)

Postoperative defecatory dysfunction 33% Maher, et al, 5th ICI 2013

Sacral Colpopexy with Prolene Mesh:

Technique: Attach Prolene mesh from vaginal apex to sacral promontory.

Success rate: 78-100% 2 year

Care study: 95% 2 year

73-78% long term

Complications: Hemorrhage may be life threatening, ureteral injury, cystotomy, proctotomy, wound infection, small bowel obstruction, nerve injury, sacral osteomyelitis, mesh erosion.

The sacral colpopexy is associated with improved urinary, defecatory, and sexual function. This procedure is also associated with a lower rate of apical recurrence and less postoperative dyspareunia than sacrospinous suspension (Cochrane Review).

C. Historical Perspective

As discussed above, traditional surgeries consisted of native tissue suture repairs that could be performed vaginally or abdominally. However, these native tissue repairs are associated with high failure rates—as high as approximately 65%—and 20% to 30% of women who undergo native tissue repair and experience recurrence will undergo reoperation (Altman 2011; Olsen 1997). Others have reported the incidence of re-operation for recurrent prolapse following native tissue repair as anywhere from 43% to 58% (Clark 2003; Whiteside 2004). Vaginal native tissue repairs have been associated with a higher failure rate than abdominal native tissue repairs, as reported by Benson et al. In 1996, Benson et al. reported the results of a long-term prospective RCT evaluating native tissue suture repairs performed via a vaginal versus abdominal approach, which demonstrated an optimal surgical effectiveness of 29% for the vaginal repair and 58% for the abdominal repair. Reoperation was required in 33% of the patients in the vaginal group and 16% of the patients in the abdominal group.

As such, in an effort to provide a more durable surgical repair, surgeons began investigating and developing new techniques and procedures that utilized synthetic mesh material and biologic grafts. Given the superior anatomic outcomes achieved by performing prolapse repairs via an abdominal approach, surgeons began performing mesh-augmented abdominal prolapse repairs (Lane 1962). In 2007, the results of a Cochrane review were published, which demonstrated superior anatomic and functional results in patients undergoing a mesh-augmented abdominal repair compared to a traditional vaginal repair with native tissue plication (Cochrane 2007).

D. Development of Gynemesh PS and Prolift

Although the abdominal mesh-augmented prolapse repairs provided better anatomic and functional results than native tissue repairs performed vaginally, the abdominal approach is more invasive and morbid and can result in wound infections and complications, herniations, seroma, abnormal scarring, pain, and nerve injury. The abdominal approach also presents a higher risk of small bowel ileus and obstruction, surgical hemorrhage, and risk of venous thromboembolism. As such, gynecologic surgeons began looking for alternatives to the abdominal mesh-augmented procedures that would be minimally invasive and provide equal or superior durability. A similar trend developed in the surgical treatment of stress urinary incontinence, leading to the development of Ethicon's TVT device, which hit the market in 1998.

Transvaginal mesh implants gained popularity in the 1990s, and by the late 1990s there was a growing body of medical literature supporting the safety and efficacy of its use for the treatment of pelvic organ prolapse and stress urinary incontinence (Julian 1996; Watson 1996; Flood 1998; Nicita 1998; Hardiman 2000; Sand 2001). With respect to the treatment of stress urinary incontinence, in addition to the literature supporting the safety and efficacy of transvaginal mesh, the TVT device offered surgeons the additional benefit of a standardized and reproducible surgical technique. Given the success of TVT and the desire of gynecologic surgeons to move towards less invasive vaginal surgeries, a group of physicians formed the TVM group in 2000 to investigate and develop a standardized and reproducible technique involving transvaginal mesh for the treatment of POP (Debodinance et al., 2004). Gynemesh PS was chosen as the material for the transvaginal mesh indicated for treatment of POP and was cleared by the FDA for such use in 2002. In 2004, a one-year study of Gynemesh PS placed vaginally or abdominally was presented at AUGS (Lucente 2004).

Prolift was released in March 2005. The Prolift device is constructed with Gynemesh PS and is accompanied by trocars that were specifically designed to provide access to the sacrospinous ligament ("SSL") for Posterior Prolift and the arcus tendinous fascia pelvis ("ATFP") for Anterior Prolift, which were established as prolapse support structures through the traditional prolapse repair procedures. Additionally, cannula were developed and included in the Prolift kit, which allowed smooth and atraumatic placement of the mesh without tissue dragging. The cannula allow the surgeon to take tension off of the arms and place the mesh flat before deployment. By the time Prolift was released in 2005, the safety and efficacy of Prolene polypropylene mesh was supported by seven years of follow-up demonstrating the safety and efficacy of TVT (Nilsson et al., 2004). Additionally, the safety and efficacy of Gynemesh PS for the treatment of POP was demonstrated by the results of a one-year study published in 2004 (Lucente 2004). By 2005, approximately 700 patients had undergone surgical implantation of transvaginal mesh (Debodinance et al., 2004; Lucente et al., 2004; Cosson et al., 2005).

II. OPINIONS

A. Prolift, constructed with Gynemesh PS, is an effective option for the treatment of pelvic organ prolapse and provides superior anatomic outcomes and quality of life improvements when compared to native tissue repair.

There is a large body of literature, including the results of numerous RCTs, demonstrating that mesh-augmented prolapse repairs utilizing Gynemesh PS and the Prolift device are associated with superior anatomical and subjective outcomes, as well as higher quality of life scores, when compared to traditional non-mesh procedures.

The largest RCT studying the outcomes of prolapse repair utilizing Anterior Prolift was reported by Altman et al. in 2011. The study randomized 389 women into two groups undergoing anterior prolapse repair. The women in one group underwent prolapse repair utilizing Anterior Prolift (n=200), while the women in the other group underwent native tissue anterior colporrhaphy (n=189). The study assessed rate of recurrence measured both objectively (POP-Q stage 0 or 1 support of the anterior vaginal wall) and subjectively (a negative response to the question "Do you experience a feeling of bulging or protrusion in the vaginal area?"). The results show that surgical repair with Anterior Prolift was associated with a lower failure rate (39.2%) than that associated with the native tissue repair (65.5%). Similar results were reported in 2011 for a RCT comparing the safety and efficacy of Prolift with traditional non-mesh vaginal prolapse repair in patients with recurrent POP (Withagen 2011). This study randomized 190 patients into two groups: 93 patients underwent prolapse repair utilizing Prolift, and 97 patients underwent a traditional non-mesh repair. At 12-month follow-up (98% of all patients reporting), anatomic failure in the treated compartment (both anterior and posterior) was significantly higher in the group of patients in the non-mesh group (45.2%) compared to the patients in the mesh group (9.6%). Both groups of patients reported a reduction of symptoms, and subjective improvement was reported in both groups (80% in the non-mesh group and 81% in the mesh group).

In another RCT comparing anatomic cure rates of Prolift repair versus native tissue repair, Halaska et al. compared recurrence and complication rates for patients undergoing sacrospinous fixation versus Prolift repair (Halaska 2012). The study randomized 168 patients with 83 undergoing SSF and 85 undergoing mesh repair with Prolift. After 12 months, prolapse recurrence

occurred in 39.4% of the patients undergoing SSF compared to 16.9% of the patients undergoing repair with Prolift. Similarly, the results of a study by El-Nazer et al. showed an anatomic cure rate of 95% following repair utilizing Gynemesh PS compared to a 70% anatomic cure rate following non-mesh repair (El-Nazer 2012). Patients in the mesh group reportedly experienced better improvement of their prolapse symptoms, such as vaginal bulge/pressure sensation.

Similarly, the results of another RCT published in 2013 compared the anatomical outcomes of patients undergoing Gynemesh PS-enforced anterior repair versus anterior colporrhaphy (Qatawneh 2013). All patients underwent a sacrospinous colpopexy and posterior fascial plication. The results of this study demonstrate that repair utilizing Gynemesh PS was associated with a higher objective success rate (79% compared to 62% in the non-mesh group); superior subjective success rates (89% compared to 76% in the non-mesh group); and lower rates of reoperation for recurrent prolapse (6% compared to 19% in the non-mesh group).

These results are consistent with those reported by Svabik et al. (2014) and da Silveira er al. (2014) for RCTs comparing Prolift to native tissue vaginal vault repairs, such as SSLF. Specifically, Svabik et al. compared the efficacy of Prolift Total versus sacrospinous fixation and reported 3% anatomical failure on examination for the patients in the Prolift group compared to 65% anatomical failure in the SSF group (Svabik 2014). In the da Silveira RCT, 184 women were randomly assigned to undergo surgical treatment for severe prolapse utilizing Prolift (n = 94) or native tissue repair (n=90). At the 1-year follow-up, anatomical response was superior in patients who had undergone anterior repair with Prolift compared to patients undergoing native tissue repair. Quality of life scores were improved in both groups, but a greater improvement in quality of life was reported in the mesh group (da Silveira 2014).

Most recently, the Cochrane Review published in 2016 noted that prolapse repair utilizing transvaginal mesh is associated with both a lower rate of recurrence on examination and lower patient awareness of prolapse when compared to recurrence and awareness of prolapse following native tissue repair (Maher 2016). Additionally, mesh repair was associated with a lower rate of repeat prolapse surgery.

B. Prolift is a safe option for the treatment of pelvic organ prolapse, and there is no statistically significant difference in the risks or incidence of complications associated with Prolift/Gynemesh PS when compared to native tissue repair.

When compared to native tissue repairs, prolapse repair utilizing Gynemesh PS/Prolift is associated with superior efficacy, with comparable or superior safety. No surgery is risk-free. There are various risks and complications associated with any surgical procedure for the treatment of POP, regardless of whether the procedure is performed vaginally or abdominally, with or without the use of mesh. It is well-known by qualified physicians who perform prolapse repairs and other pelvic floor surgeries that potential complications following any prolapse repair surgery include, but are not limited to: infection; bleeding; injury to adjacent organs, nerves, tissue, vessels; pain (pelvic, vaginal, groin); dyspareunia; wound complications; tissue contraction; scarring; urinary complaints; recurrence of prolapse; and surgery to address recurrence and/or complication.

i. Erosion/Exposure

The only potential complication associated with POP repair utilizing mesh that is not associated with native tissue repairs is the risk of mesh erosion/exposure/extrusion. Mesh exposure

is a type of wound complication that results from a breakdown or opening of the vaginal incision after surgery. An exposure can also occur after the incision has healed due to the gradual thinning, drying and inflammation of the tissues in the vaginal wall associated with menopause. Mesh exposure is a known risk associated with any surgery utilizing mesh, regardless of the operative approach (vaginal or abdominal) (Heinonen 2016).

By definition, the complication of *mesh* exposure cannot be associated with a *non-mesh* prolapse repair. However, erosions and wound complications are not unique to the use of mesh and occur at similar rates following native tissue repair (Toglia 2008; Abed 2011; Yazdany 2010; Sokol 2012; Svabik 2014). In 2008, Toglia et al. published the results of a study of patients undergoing SSLS and reported a suture-related complication rate of 36%, with 25% of those patients undergoing suture removal. Similarly, in 2010, Yazdany reported the results of a study showing a 44.6% rate of suture-related complications, which included a 36.1% rate of suture erosion in patients undergoing USLS. In 2012, Sokol et al. reported the results of a RCT comparing vaginal prolapse repairs with and without mesh and found a 15.6% rate of mesh exposure in the mesh group and a 15% rate of suture exposures in the non-mesh group (Sokol 2012). In a RCT comparing the outcomes of mesh (Prolift) and native tissue repair (SSF), 8% of the patients undergoing repair using Prolift developed mesh exposure, and 15% of the patients undergoing SSF developed a wound complication (vaginal blood spotting due to granulation tissue) (Svabik 2014).

Furthermore, erosion is not a complication that is unique to synthetic grafts, such as polypropylene mesh. In 2011, Abed et al. published the results of an SGS Systemic Review of 110 studies reporting on graft erosions and found a 10.3% rate of erosion for synthetic mesh and a 10.1% rate of erosion for biological grafts (Abed 2011). The SGS Systemic Review included 16 studies reporting on wound granulation and found a wound granulation rate of 6.8% associated with synthetic grafts and 9.1% with biologic grafts.

There have been numerous RCTs and other studies evaluating and comparing complication rates associated with mesh surgery and non-mesh surgery, which demonstrate that prolapse repair with Gynemesh PS/Prolift is not associated with a statistically significant difference in the rate or severity of overall complications or a negative impact on patient quality of life. In fact, even in studies that report a higher exposure rate associated with mesh surgery compared to native tissue repair, Prolift was associated with significantly higher improvement in quality of life and patient satisfaction (da Silveira 2014).

ii. Urinary Dysfunction

With any surgery to treat POP, there is a risk that the patient will develop de novo urinary complaints, such as voiding disorders, urgency, detrusor overactivity or overactive bladder. The 2016 Cochrane Review reported the results of three studies assessing this outcome following mesh surgery compared to non-mesh surgery (Maher 2016). There was a total of 236 participants in the three studies—120 undergoing repair with mesh and 116 undergoing native tissue repair. The results of the Cochrane Review demonstrate no statistically significant difference in the rate of de novo urinary complaints between the mesh (10/120, 8%) and non-mesh (13/116, 11%) groups (Halaska 2012; Al-Nazer 2007; De Tayrac 2008). The Cochrane Review also reported the results of two studies assessing this outcome (de novo voiding disorders, urgency, detrusor overactivity or overactive bladder) in patients undergoing prolapse repair using a biological graft compared to native tissue repair. Of the 40 women who underwent a biological graft repair, 12% (5/40) reported

de novo urinary complaints, and 15% (8) of the 53 women undergoing native tissue repair reported de novo urinary complaints (Feldner 2010; Gandhi 2005).

The Cochrane Review reported that there is low-quality evidence indicating that women undergoing prolapse repair with mesh are more likely to develop de novo stress urinary incontinence than patients undergoing native tissue repair (Maher 2016). Maher et al. reported that their review suggests that if 10% of patients developed de novo stress urinary incontinence after undergoing native tissue repair, then 10% - 17% of patients would develop de novo stress urinary incontinence following prolapse repair utilizing mesh.

However, association does not equal causation. I do not believe that the literature supports a conclusion, to a reasonable degree of medical or scientific certainty, that prolapse repair utilizing Gynemesh PS/Prolift causes a higher rate of de novo stress urinary incontinence than native tissue repair. I believe that the association between de novo stress urinary incontinence and prolapse repair utilizing transvaginal mesh is due to the superior anatomical cure rate associated with Gynemesh PS/Prolift compared to native tissue repair, combined with the prevalence of occult, or "masked," stress urinary incontinence. As noted above, masked stress urinary incontinence is commonly reported in up to 65% of women who have undergone a prolapse repair procedure (Reena 2007). Additionally, as described above, the anatomic failure rate of prolapse repair utilizing transvaginal mesh, such as Gynemesh PS/Prolift (3%), is significantly lower than the anatomic failure rate that has been reported following native tissue repair (65%) (Svabik 2014).

In women with masked incontinence, the restoration of normal pelvic anatomy following a surgical prolapse repair triggers the onset of symptomatic stress urinary incontinence. In other words, in up to 65% of women with POP, the prolapse is the only thing preventing her from experiencing pre-operative stress urinary incontinence. As such, it is not surprising that prolapse repair utilizing Prolift, which has been associated with very high anatomic cure rates of up to 97%, is associated with a higher rate of de novo stress urinary incontinence. Conversely, patients undergoing native tissue repairs, which have high anatomic failure rates of up to 65%, are less likely to report symptoms of new onset stress urinary continence because the recurrence of prolapse and continued abnormal pelvic anatomy can result in kinking of the urethra, masking the patient's stress urinary incontinence (de Landsheere 2012; Svabik 2014).

iii. Dyspareunia

Dyspareunia is a common complaint in reproductive-aged women, especially post-menopausal women and/or women with pelvic floor disorders, and has been reported in up to 54.5% of women aged 15-49 (Lowman 2008). Dyspareunia is a risk of any prolapse surgery, with or without mesh. The results of the recent Cochrane Review demonstrate that there is no statistically significant difference in the incidence of de novo dyspareunia in patients undergoing mesh repair compared to native tissue repair (Maher 2016). This is consistent with the results of numerous studies showing that the incidence of dyspareunia associated with Prolift and Gynemesh PS is comparable to the dyspareunia rate associated with native tissue repairs.

Early studies raised concern that the rate of de novo dyspareunia associated with Prolift may be unacceptably high. As such, Lowman et al. evaluated all of the Prolift cases performed between August 2005 and August 2007 in order to determine the rate of de novo dyspareunia associated with Prolift (Lowman 2008). In 2008, the results of that evaluation were published, reporting a 16.7% rate of de novo dyspareunia following prolapse repair with Prolift, which is

lower than or comparable to the rate of de novo dyspareunia following native tissue repair. Lowman et al. analyzed the results of the five largest studies assessing de novo dyspareunia as a primary outcome following native tissue repairs and reported an incidence of de novo dyspareunia ranging from 14.5-36.1% (Lowman 2008).

Subsequent studies, including RCTs, have confirmed that there is no statistically significant difference in the rate of de novo dyspareunia or sexual dysfunction following prolapse repair with mesh versus native tissue repair (Svabik 2014). In 2012, Sokol et al. reported a higher rate of de novo dyspareunia associated with native tissue repair (21.4%) compared to mesh prolapse repair (9.1%), noting that the difference was not statistically significant.

In 2013, Dietz and Maher published the results of a meta-analysis of studies evaluating dyspareunia rates associated with mesh and non-mesh prolapse repairs, reporting no statistically significant difference in the incidence of de novo dyspareunia (mesh 10.6% vs. 11.8% native tissue). Similarly, there were no statistically significant differences in the rates of post-operative dyspareunia or PISQ scores (Dietz and Maher 2013). Subsequent RCTs have reported a numerically higher incidence of de novo dyspareunia associated with native tissue repair as compared to mesh repairs, but the differences were not statistically significant (El-Nazer 2012; da Silveira 2014).

Recently, an article by Meyer et al. was published, reporting long-term outcomes in women who had undergone prolapse repair with Prolift. Meyer et al. reported a dyspareunia rate of 36% (Meyer 2016). However, as recognized by the authors, this finding is of limited value and does not represent an unacceptably high complication rate for two reasons. First, because the authors did not assess baseline dyspareunia, no conclusions can be drawn as to the rate of *de novo* dyspareunia associated with Prolift. Second, Meyer et al. noted that dyspareunia is not a complication that is unique to prolapse repairs utilizing mesh, noting that the incidence of dyspareunia in patients undergoing native tissue repair is between 19% and 37% (Meyer 2016).

C. Prolift utilizing Gynemesh PS is not defective in its design, and there is no reliable data or literature demonstrating that Plaintiffs' proposed alternative designs are safer and more effective in the treatment of pelvic organ prolapse.

In terms of evaluating the safety and efficacy of various mesh materials, the biocompatibility of a particular mesh must be assessed. A biocompatible mesh is one with the ability to perform its intended function of supporting the weakened or damaged pelvic floor, with the desired degree of incorporation into the host, without eliciting undesirable local or systemic effects in that host (Williams DF 2008). There are four basic materials that are used to make almost all mesh materials: polypropylene, polyethylene-terepthalate, polytetrafluor-ethylene, and polyvinylidene-fluoride. Factors to consider in the assessment of a mesh material's biocompatibility include the material's pore size, weight, elasticity and filamental structure.

Dr. Amid developed surgical mesh classifications that are widely accepted today (Amid 1997). Type 1 macroporous mesh is universally considered the most biocompatible mesh with the least propensity for infection (Ford Cochrane Review 2015). According to Dr. Amid's classification, in order to be considered a Type 1, macroporous mesh, a mesh must have a pore size of larger than 75 microns. A pore size of greater than 75 microns allows macrophages, fibroblasts, neovasculature, and collagen to enter the pore (Amid 1997). The pore size of a mesh material affects the inflammatory response and tissue integration to be expected following

implantation of the mesh. If the pore size of a mesh is smaller than 75 microns, fibroblast infiltration is restricted, which can result in encapsulation. The Prolene polypropylene mesh used in Ethicon's TVT device is a type 1 macroporous mesh, and its durability, safety and efficacy have been demonstrated and supported by data up to 17 years (Nilsson et al., 2013).

Like the Prolene polypropylene mesh used in TVT, Gynemesh PS is classified as a macroporous type 1 monofilament polypropylene mesh. The pore size of Gynemesh PS is 2.4 mm (2,400 microns) and is a lightweight mesh of 42 g/m2. The TVM group continued working to develop a standardized procedure utilizing the Gynemesh PS, which ultimately led to the release of Prolift in 2005. As noted above, by the time Prolift was released, approximately 700 patients had undergone implantation of transvaginal mesh, and the literature included 7-year data supporting the safety and efficacy of the Prolene polypropylene mesh in TVT, as well as 1-year data demonstrating the safety and efficacy of Gynemesh PS (Nilsson et al., 2004; Lucente 2004; Debodinance et al., 2004; Lucente et al., 2004; Cosson et al., 2005).

Prolift has been studied more than any other medical device for the treatment of POP. Specifically, Prolift, which utilizes Gynemesh PS, has been the subject of more than 100 studies, including several RCTs comparing surgical outcomes of Prolift repairs versus traditional native tissue repairs, the results of which establish that Prolift is safe, effective, and provides superior anatomic and subjective outcomes, as well as quality of life improvements.

Conversely, although some of Plaintiffs' experts in this litigation have offered opinions that Ultrapro and PVDF are safer alternatives to the Gynemesh PS/Prolift, there is no reliable data or literature demonstrating that these proposed alternatives are safer and equally or more effective than Gynemesh PS/Prolift in the treatment of POP. In fact, two RCTs evaluated the use of synthetic absorbable mesh for use in the surgical treatment of pelvic organ prolapse, and neither RCT demonstrated any benefit to the use of absorbable mesh (Weber 2001; Madhuvrata 2011). Vypro mesh, which is a blend of Prolene and Vicryl, was considered and evaluated by the TVM Group, but it was determined that Vypro was not well-tolerated (Jacquetin 2004). Ultrapro was ultimately chosen as the mesh to use in the later-released Prolift +M device. However, Prolift +M has been the subject of a number of studies evaluating its safety and efficacy, and none of these studies demonstrate that there are any statistically significant differences in the rates of complications, anatomic outcomes, or functional outcomes associated with Prolift +M as compared to Prolift.

D. The risks associated with Prolift and Gynemesh PS are virtually identical to the risks associated with native tissue repair, and these risks should be known by physicians performing prolapse repairs with and without mesh.

As discussed above, no surgery is risk-free, and surgery to treat POP is no exception. All vaginal surgeries, including surgical repair of POP, are associated with numerous risks that are taught to physicians in medical school and throughout their medical training, such as: injury to adjacent organs, nerves, tissues; infection; bleeding; pelvic, vaginal and/or groin pain, including pain with intercourse; wound complications; tissue contraction; scarring; urinary complaints; recurrence of the underlying condition; and surgery to repair one or more of possible complication (*see also* Table 1).

Table 1

Potential Risks of Non-Mesh and Mesh POP Surgeries

NON-MESH	MESH
Acute and/or Chronic Pain with Intercourse	**Acute and/or Chronic Pain with Intercourse**
Acute and/or Chronic Pain	**Acute and/or Chronic Pain**
Vaginal Scarring	**Vaginal Scarring**
Infection	**Infection**
Urinary Problems (urinary frequency, urgency, dysuria, retention, or obstruction; incontinence)	**Urinary Problems** (urinary frequency, urgency, dysuria, retention, or obstruction; incontinence)
Organ / Nerve Damage	**Organ / Nerve Damage**
Bleeding	**Bleeding**
Wound Complications	**Wound Complications**
Inflammation	**Inflammation**
Fistula Formation	**Fistula Formation**
Neuromuscular Problems (in pelvic floor muscles, lower extremities, and/or abdominal area)	**Neuromuscular Problems** (in pelvic floor muscles, lower extremities, and/or abdominal area)
One or more surgeries to treat an adverse event	**One or more surgeries to treat an adverse event**
Recurrence or Failure (prolapse in untreated compartment)	**Recurrence or Failure** (prolapse in untreated compartment)
Foreign Body Response (sutures)	**Foreign Body Response** (mesh)
Erosion/Exposure/Extrusion (sutures)	**Erosion/Exposure/Extrusion** (mesh)
Contraction/Shrinkage of tissues	**Contraction/Shrinkage of tissues**

[2]

Pelvic floor surgeons performing POP surgeries should be aware of these risks as a result of their basic medical and surgical training. Additionally, the risks associated with prolapse repairs and vaginal surgeries in general have been reported in the literature for decades and should be known by the intended users of Gynemesh PS/Prolift (Francis & Jeffcoate 1961; Lane 1962; Benson 1996; Iglesia 1997). Further, these risks are discussed and analyzed by professional societies in reviews, guidelines and position statements, as well as statements and notices issued by the FDA. Information regarding the risks of a particular procedure must be made available to physicians from various sources because, unlike surgical procedures involving the use of a medical device, there is no Instructions for Use ("IFU") or other document to supplement the physician's own knowledge of the risks associated with native tissue repairs.

As a physician performing surgical repairs for the treatment of pelvic organ prolapse and stress urinary continence as part of my typical practice, my knowledge of the risks of these procedures is based upon my knowledge and experience as a physician that I began developing in medical school and continued throughout my medical training, continuing education and professional practice, as well as my review of the literature.

With respect to surgical repairs involving the implantation of a medical device, such as Prolift, I review the IFU for the device to learn how to use the device and its components or accessories and to ascertain any potential associated risks that are unique to the device. As discussed above, the only risk associated with the use of transvaginal mesh in the surgical treatment of pelvic organ prolapse that is not also a risk of native tissue repair is mesh erosion/extrusion/exposure. Notably, however, erosion is a commonly-known risk that is associated with all foreign bodies implanted in the human body. Exposure of Prolene sutures has been a well-known risk associated with suture repair for decades. Despite the fact that the implantation of any foreign body is associated with a risk of exposure/erosion/extrusion of that

foreign body, this risk is identified in the IFUs for the Ethicon devices at issue in this litigation: "Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction."

Additionally, the use of surgical instruments included in the Prolift kit can result in injuries to adjacent organs, vessels and nerves. Although this should be an obvious and known risk to the intended users of Prolift, the Prolift IFU expressly warns: "Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair." The IFU also includes a precaution to the intended users of Prolift: "The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks."

I have read the IFUs for the Ethicon products at issue in this litigation and find them to be clear and useful. It is my opinion, based upon my experience performing these procedures, that the information contained in the IFUs is adequate to enable me to determine whether the device is the appropriate treatment option for my patient and to inform me about the device, its associated risks, and how to use the device in the procedure.

III. CONCLUSION

Based upon my review of the medical literature and my experience utilizing Gynemesh PS/Prolift for the surgical treatment of pelvic organ prolapse in my patients, it is my opinion, to a reasonable degree of medical and scientific surgery, that Gynemesh PS and Prolift are safe and effective devices for their intended use in the surgical treatment of pelvic organ prolapse. There is a large body of reliable literature that is generally accepted by the medical community establishing that Gynemesh PS/Prolift provide superior anatomic and functional outcomes when compared to native tissue repairs, with no statistically significant difference in the nature and incidence of complications.

The incidence and severity of any complication in a particular patient is extremely variable and dependent upon various patient-specific considerations. For example, some patients are more likely to develop abnormal scarring than others, while other patients may be more likely to develop a mesh exposure or experience pain with intercourse. As such, in weighing the various treatment options it is the physician's duty to perform a risk-benefit analysis for each individual patient, taking into account the patient's medical and surgical history, social history, co-morbidities and general health at the time of surgery. Gynemesh PS is the most-studied device utilized in the surgical treatment of pelvic organ prolapse and the Prolene polypropylene mesh in Ethicon's TVT device, which is constructed using the same material from which Gynemesh PS is made, is widely known to be safe for implantation in the human body and has 17-year data supporting its use in the treatment of pelvic floor disorders.

Additionally, the Gynemesh PS used in Prolift is classified as a type 1, macroporous, monofilament polypropylene mesh, with a pore size of 2400 microns, far exceeds the minimum pore size necessary to allow appropriate infiltration of macrophages, fibroblasts, leukocytes, blood

vessels and collagen. Gynemesh PS's large pore size promotes the tissue host ingrowth necessary for the mesh to perform its intended function of supporting the weakened tissues in the pelvic floor and restoring normal pelvic anatomy while minimizing the risk of infection. When used in the treatment of pelvic organ prolapse, Gynemesh PS is a lightweight mesh that is able to provide support for the weakened pelvic floor tissues while retaining flexibility to withstand the forces in the pelvis associated with movement and daily activities.

Further, there is not sufficient reliable data or literature supporting the theory that Ultrapro, PVDF, and/or Vypro mesh are safer and equally or more effective alternatives for use in the Prolift device for the treatment of pelvic organ prolapse. Vypro was evaluated as a potential material for use in Prolift, but it was determined that it was not well-tolerated and, therefore, was not a viable option. Although Ultrapro is now utilized in the Prolift +M device, the literature demonstrates that there is no statistically significant difference in the safety and efficacy of Prolift +M as compared to Prolift. In my practice, Gynemesh PS and Prolift provide superior anatomic outcomes with no statistically significant difference in the incidence of complications. All tissue contracts with healing. In my practice, I have never witnessed curling, folding, roping, fraying or degradation of the Gynemesh PS in Prolift in vivo, nor have I seen or treated any patient for a complication caused by in vivo deformation of the mesh. This is consistent with my review of the medical literature, which does not reliably support the theory of Plaintiffs' experts that the Gynemesh PS in Prolift has a propensity to become deformed and degraded in vivo.

Finally, the risks associated with the surgical repair of pelvic organ prolapse utilizing Gynemesh PS and Prolift are nearly identical to the risks associated with native tissue repair and should be known by pelvic floor surgeons as a result of their medical and professional education and training, as well as review of the relevant medical literature. Additionally, the only complication unique to the use of Gynemesh PS/Prolift is mesh erosion/exposure/extrusion, which is a risk associated with the implantation of any foreign material in the human body and is expressly identified as an associated risk in the product IFUs for these devices. It is my opinion, based upon my experience in prescribing and implanting these devices to treat pelvic organ prolapse in my patients, that the information contained in the product IFUs is sufficient to inform me how to use the device and to enable me to perform the risk-benefit analysis needed to make an informed prescribing decision.

HARRY WALLACE JOHNSON, JR., M.D.
Curriculum Vitae

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PERSONAL INFORMATION:

Born:	September 17, 1956
Citizenship:	USA
Martial Status:	Married to Mary Jo Johnson, M. D.
Children:	Michael (6/18/89), Molly (12/31/90), Kathryn (1/15/94)

EDUCATION:

Undergraduate:	1978	Duke University B.A. - Management Science
	1980	University of North Carolina at Greensboro B.A. - Biology Honors - Beta Beta Beta Biology National Honor Society
Medical:	1984	Wake Forest University Medical Center Bowman Gray School of Medicine - M.D.
Postgraduate:	1984-85	Wake Forest University Medical Center North Carolina Baptist Hospitals, Inc. Internship - General Surgery
	1985-89	University of Maryland Medical Center Department Obstetrics and Gynecology
	1985-86	Internship
	1986-87	Junior Assistant Resident
	1987-88	Senior Assistant Resident
	1988-89	Administrative Chief Resident
	1992-93	Fellowship - Greater Baltimore Medical Center Pelvic Surgery, Operative Endoscopy, Urogynecology

LICENSURE:

Maryland State Board of Medical Examiners (1989-Present)
FLEX

SPECIALTY BOARDS:

Diplomate, American Board of OB-GYN (12/13/1991)
Recertification - 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013
Female Pelvic Medicine and Reconstructive Surgery - 2015

PROFESSIONAL MEMBERSHIP:

American College of Obstetricians and Gynecologists Fellow
American Association of Gynecologic Laparoscopists
American Urogynecology Society
Association of Professors in Gynecology and Obstetrics
International Urogynecological Society
Society of Pelvic Reconstructive Surgeons
Fellow American College of Surgeons
Medical and Chirurgical Faculty of Maryland
Maryland OB/GYN Society
Baltimore City Medical Society
Douglass Obstetrical and Gynecology Society

CERTIFICATIONS:

Basic Life Support
Advanced Trauma Life Support
Armed Forces War Surgery/Skills Enhancement

MILITARY SERVICE:

United States Navy (1989-1992)
LCDR. USNR - MC
National Naval Medical Center, Bethesda, MD

MILITARY AWARDS (U.S. NAVY):

Navy Unit Commendation Medal
Meritorious Unit Commendation
Navy Commendation Medal
South West Asia Campaign Medal with 2 Bronze Stars
National Defense Medal
Sea Service Award
Kuwait Liberation Medal

ACADEMIC POSITIONS:

University of Maryland, School of Medicine
Associate Professor, Department of Surgery, Division of Urology (2010-present)
Head, Division of Urogynecology and Pelvic Reproduction (2003-present)
Associate Vice Chairman, OB-GYN (2003-present)
Associate Professor (1999-present)
Assistant Professor (1995-1999)
Clinical Instructor (1992-1995)
Director OB-GYN Residency Training Program (1993-2004)
Interim Head, Division of Gyn-Oncology

Uniformed Services University of the Health Sciences
F. Edward Herbert School of Medicine
Clinical Instructor (1989-1991)
Assistant Professor (1991- 1992)

CURRENT MAJOR RESPONSIBILITIES:

1. Associate Vice Chairman
   Department of Ob/Gyn and Reproductive Sciences
   University of Maryland Medical System
2. Associate Professor
   Head, Division of Urogynecology, Pelvic Reconstructive Surgery
   University of Maryland Medical System
3. Director of Gynecology
   Baltimore V.A. Medical Center
4. Consultant - Urogynecology and Endoscopic Surgery
   Mercy Medical Center

PROFESSIONAL AWARDS:

OB-GYN Department Teacher of the Year Award (1994)
Baltimore's Best Doctor listing, ***Baltimore Magazine*** (1995, 1997, 2002, 2004, 2006, 2008, 2009, 2010, 2011, 2013)
The Best Doctors in America: Southeast Region (1996)
Audiovisual "Laparoscopic Pelvic Anatomy", ACOG second prize (1996)
APGO Excellence in Teaching Award (1996)
Best Doctors in America (2003-present)
Guide to America's Top Obstetricians and Gynecologists listing (2006 Edition- present)
Super Doctors – Washington D.C. (2011)

HOSPITAL MEDICAL STAFF APPOINTMENTS:

2014-Present	Attending Staff, University Midtown, Baltimore, MD
2014-Present	Attending Staff, St. Joseph Medical Center, Towson, MD
2010-Present	Attending Staff, Upper Chesapeake Medical Center, Bel Air, MD
2010-Present	Attending Staff, Baltimore Washington Medical Center, Glen Burnie, MD
2004-2012	Attending Staff, St. Joseph Medical Center, Towson, MD
1992-Present	Attending Staff, University of Maryland Hospital, Baltimore, MD
1992-Present	Attending Staff, Mercy Medical Center, Baltimore, MD
1992-2011	Attending Staff, Greater Baltimore Medical Center, Towson, MD
1996-Present	Attending Staff, VA Medical Health Care System, Baltimore, MD
1991-1994	Associate Staff, St. Agnes Hospital, Baltimore, MD
1991-1994	Associate Staff, Prince George's Hospital, Cheverly, MD
1989-1992	Attending Staff, National Naval Medical Center, Bethesda, MD (Director of Ambulatory Care, Director of Urodynamic Testing Center)
1989-1992	Attending Staff, Naval Hospital, Patuxent River, MD
1989-1990	Attending Staff, Naval Hospital, Yakoska, Japan
1990-1991	Head Division OB-GYN, USNS Comfort Hospital Ship

ACADEMIC HOSPITAL COMMITTEES:

National Naval Medical Center, Committee for the protection of Human Subjects (1989-1992)

University of Maryland Medical System:

UMMC Credentials Committee (1993-present)
UM School of Medicine Faculty Senate (1993-1994)
UM School of Medicine Longitudinal Ambulatory Committee (1993-1997)
UM School of Medicine Graduate Medical Education Committee (1994-1996)
UM School of Medicine Graduate Medical Education Committee Chair (1996-2002)
UM School of Medicine Graduate Medical Education Policy Committee (1996-2002)

COMMITTEES: University of Maryland Medical System

UMMC Medical Executive Committee (1996-present)
UMMC Women's Services Oversight Group (1996-present)
UMMC Administrative Affairs Committee (1997-present)
UMMC Operating Room Committee (1997-2009)
University of Maryland Obstetrical and Gynecological Associates, P.A.
Member, Board of Directors (1996-present)
Vice President (1996-present)
UMMC Chief Resident Forum (1998-2000)
UMMC Performance Improvement Steering Committee (1999-present)
UMMC Institutional Advancement/Outreach Subcommittee (2000-2001)

Mercy Medical Center:

Physician Leadership Group for the Women's Center (1995-1998)
OB-GYN Residency Steering Committee (1997-2004)

SUPERVISORY EXPERIENCE:

Fellows:

Urogynecology, Pelvic Reconstructive Surgery Fellow
Barbara Plucknett, MD, 1996
Paul Marshburn, MD, 1996
Aileen Yee, MD, 1997
Salil Khandawala, MD, 1997
Kio Nihira, MD, 1998
Mark Ellerkman, MD, 1999
Jerome Buller, MD, 2000
Nga Turner, MD, 2000
Kenneth Leffler, MD, 2001
James Dunn, MD, 2001
Joan Bloomquest, MD, 2001
Andrew McBride, MD, 2002
Janet Li, MD, 2003
Matthew Fagan, MD, 2004
Danita Akingba, MD, 2005
Folusho Tugbiyele, MD, 2006
Tatiana V. Sanses, MD, 2007
Kay A. Hoskey, MD, 2008
Maria D. Hernandez, MD, 2009
Toni R. Slyvester, MD, 2011

Residents

1993 – 2004	Director of Department of Obstetrics, Gynecology and Reproductive Sciences Residency Training Program
1993 - Present	Faculty Attending (one week/month) Gynecology Service, University of Maryland Medical Center
1993 - 2004	OB/GYN Morbidity Mortality Conference (weekly)
4/97 & 4/98	Baltimore/Washington Ethics Retreat, Group facilitator

Medical Students

1993 - 2005 Core Lecturer, Clinical Care Rotation in Obstetrics and Gynecology, University of Maryland School of Medicine, (2-3 lectures every six weeks)

1990 -present Preceptor, Third year Clinical Care Rotation, Obstetrics and Gynecology, University of Maryland School of Medicine

1993 - 2005 Course Master - Fourth Year Elective Rotation, Gynecologic Surgery

1993 - 2005 Physical Diagnosis Course to Sophomore Students (Breast Exams)

RESEARCH GRANTS:

1. Urinary Incontinence Treatment Network: Continence Treatment Centers
   Co-PI, 7/1/01 to 6/30/05
   Grant: DK-01-018
   Grant: HD-00-013
   Direct Costs: $857,904

2. Effects of Stretch on IC and Normal Urothelia
   Co-investigator, 6/1/01 to 5/31/06
   Grant R01-DK59441-01

3. Race, Lipoprotein Lipase and Obesity after Menopause
   Co-Investigator, 4/1/03 to 3/31/09
   Grant R01-AG20116 NIH/NIA
   $2,276,038

4. Gynecology Services for Female Veterans, Veterans Administration Medical Center
   Principal Investigator, 1996-present
   Direct Costs: $80,504

PUBLICATIONS:

Perdue PW, Johnson Jr. HW, Stafford PW. Intestinal Obstruction Complicating Pregnancy. The American Journal of Surgery. 1992;104:384-88.

Chai TC, Zhang CO, Shoenfelt JL, Johnson Jr. HW, Warren JW, Keay S. Bladder Stretch Alters Urinary Heparin-Binding Epidermal Growth Factor and Antiproliferative Factor in Patients with Interstitial Cystitis. The Journal of Urology. 2000;163:1440-44.

Richter,HE, Burgio,KL, Brubaker,L, Moalli,PA, Markland,AD, Mallet,V, Menefee,SA, Johnson,HW, Boreham,MK, Dandreo,KJ, Stoddard,AM. Factors associated with incontinence frequency in a surgical cohort of stress incontinent women. Am J Obstet Gynecol, 2005;193:2088-93.

Urinary Incontinence Treatment Network. Design of the stress incontinence surgical treatment efficacy trial (SISTEr). Urology, 2005;66:1213-17.

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Albo,ME, Richter,HE, Brubaker,L, Norton,P, Kraus,SR, Zimmern,PE, Chai,TC, Zyczynski,H, Diokno,AC, Tennstedt,S, Nager,C, Lloyd,LK, FitzGerald,MP, Lemack.GE, Johnson,HW, Leng,W, Mallett,V, Stoddard,AM, Menefee,S, Varner,RE, Kenton,K, Moalli,P, Sirls,L, Dandreo,KJ, Kusek,JW, Nyberg,LM, Steers,W. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med, 2007;356:2143-55.

Burgio,KL, Kraus, SR, Menefee, S, Borello-France, D, Corton, M, Johnson, HW, Mallet, V, Norton, P, FitzGerald, MP, Dandreo, K, Richter, H, Rozanski, T, Albo, M, Zyczynski, HM, Lemack, GE, Chai, TC, Khandwala, S, Baker, J, Brubaker, L, Stoddard, AM, Goode, PS, Nielsen-Omeis, B, Nager, C, Kenton, K, Tennstedt, SL, Kusek, JW, Chang, D, Nyberg, LM, Steers, W. Behavioral Therapy to Enable Women with Urge Incontinence to Discontinue Drug Treatment. Ann Intern Med, 2008 Aug 5;149(3): 161-9.

Urinary Incontinence Treatment Network. The Trial Of Mid-Urethral Slings (TOMUS): Design and Methodology. J Applied Res. 2008 Jan, 8:1-13.

Brubaker,L, Stoddard,A, Richter,H, Zimmern,P, Moalli,P, Kraus,SR, Norton,P, Lukacz,E, Sirls,L, Johnson,HW. Mixed Incontinence: Comparing Definitions in Women Having Stress Incontinence Surgery. Neurourol Urodynam, 2009 April; 28(4): 268-73.

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FitzGerald, Johnson,HW, Kraus,SR, Lemack,GE, Mallett,V, Stoddard, Tennstedt,SL, Zyczynski. Patient Expectations and Their Relationship to Baseline Symptoms, Patient Locus of Control and Outcomes. Submitted ICS, 2009.

Richter,HE, Albo,ME, Zyczynski,HM, Kenton,K, Norton,PA, Sirls,LT, Kraus,SR, Chai,TC, Lemack,GE, Dandreo,KJ, Varner,RE, MenefeeS, GhettiC, Brubaker,L, Nygaard,I, Khandwala,S, Rozanski,TA, Johnson,H, Schaffer,J, Stoddard,AM, Holley,RL, Nager,CW, Moalli,P, Mueller,E, Arisco,AM, Corton,M, Tennstedt,S, Chang,TD, Gormley,EA, Litman,HJ. Retropubic versus Transobturator Midurethral Slings for Stress Incontinence. N Engl J Med, 2010 Jun 3; 362(22): 2066-76.

Brubaker,L, Lukacz,ES, Burgio,K, Zimmern,P, Norton,P, Leng,W, Johnson,H, Kraus,S, Stoddard,A. Mixed Incontinence: Comparing Definitions in Non-Surgical Patients. Neurourol Urodyn, 2011 Jan; 30(1): 47-51.

Nager,CW, Brubaker,L, Litman,HJ, Zyczynski,HM, Varner,RE, Amundsen,C, Sirls,LT, Norton,PA, Arisco,AM, Chai,TC, Zimmern,P, Barber,MD, Dandreo,KJ, Menefee,SA, Kenton,K, Lowder,J, Richter,HE, Khandwala,S, Nygaard,I, Kraus,SR, Johnson,HW, Lemack,GE, Mihova,M, Albo,ME, Mueller,E, Sutkin,G, Wilson,TS, Hsu,Y, Rozanski,TA, Rickey,LM, Rahn,D, Tennstedt,S, Kusek,JW, Gormley,EA. A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery. N Engl J Med, 1012 May 24;-366(21): 1987-97.

ABSTRACTS:

Johnson,Jr.,HW. Laparoscopic Burch Colposuspension in Fresh Cadavers. American Urogynecologic Society, New Orleans, LA. 1996.

Johnson,Jr.,HW, Bent,AE, Rogers,Jr.,RM, McLennan,M, Plucknett,B. Laparoscopic Retroperitoneal Anatomy Using Fresh Cadavers. American College of Obstetrics and Gynecology, District IV, Lake Buena Vista, FL. 1996.

Johnson,Jr.,HW, Bent,AE, Rogers,Jr.,RM, McLennan,M, Plucknett,B. Laparoscopic Dissection of the Female Pelvis using Fresh Female Cadavers. American Urogynecologic Society, New Orleans, LA. 1996.

Johnson Jr. HW, Bent, AE, Rogers,Jr. RM, McLennan, M, Plucknett, B. Laparoscopic Anatomy: A Correlative Examination of Pelvic Anatomy in Fresh Cadavers and Live Operative Procedures. American Urogynecologic Society, New Orleans, LA. 1996.

Howell, Jesse, Johnson,HW, Sirls,L, Dandreo,K, Gruss, Hall. Learning from the SISTEr trial: findings from the Patient Burden Survey at study completion. Oral Poster, ICS, 2009.

AUDIOVISUALS:

Laparoscopic Pelvic Anatomy. 1996 (Awarded 2nd prize by ACOG)

INVITED SPEECHES/PRESENTATIONS:

"Benign Conditions of the Ovary & Fallopian Tube", resident/faculty seminar 3/16/94

"Complications in Endoscopic Surgery", St. Joseph Hospital Grand Rounds, OB-GYN Dept., Baltimore, MD 6/2/95

"Urinary Incontinence" and "Advances in Laparoscopic Surgery" , Advances in Health Care for Women Over 40, Wash, DC 6/17/94

"Dysfunctional Uterine Bleeding", 20th Annual Family Medicine Review Course, Ocean City, MD 6/21/94
"Techniques to Decrease Surgical Morbidity", 13th Annual Update in Obstetrics & Gynecology, Annapolis, Maryland 6/23/94

"Urinary Incontinence", University of Maryland Hospital, Women's Health Month, Baltimore, MD 9/23/94

Urogynecology", Mercy Medical Center Grand Rounds, OB-GYN Dept., Baltimore, MD 11/3/94

"Vaginal Vault Prolapse", St. Joseph Hospital Grand Rounds, Baltimore, MD 12/1/94

"Vaginal Prolapse", Mercy Medical Center Grand Rounds, OB-GYN Dept., Baltimore, MD 2/8/95

"Pelvic Floor Reconstruction", University of Maryland Hospital Grand Rounds, Urology Dept., Baltimore, MD 5/11/95

"Vaginal Vault Prolapse", Anne Arundel Medical Center, Annapolis, MD 5/25/95

"Vaginal Hysterectomy (Laparoscopic Assisted)", Controversies in GYN: Medical & Surgical Management of Uterine Fibroids, Washington DC 6/3/95

"Vaginal Vault Prolapse", University of Maryland Hospital Grand Rounds, OB-GYN Department, Baltimore, MD 6/23/95

"How to Approach the Patient in Menopause:, Perry Point VA Hospital, MD 9/12/95

"Abnormal Uterine Bleeding", Sheraton Inner Harbor, Dept. CME Course, Baltimore, MD 9/29/95

"Ureteral Injury in Gynecologic Surgery", St. Joseph Hospital Grand Rounds, Baltimore, MD 12/7/95

“Urogynecology”, Basic Genetics and Women’s Health Issues for the Primary Care Physician, Towson, MD 11/22/96

“Urinary Incontinence”, St. Joseph Hospital Grand Rounds, Baltimore, MD 4/3/97

“Urogynecology: A New Look at Old Problems”, Reproductive Health Update, Anne Arundel Community College, Baltimore, MD 4/25/97

"Clinical and Surgical Management of Female Incontinence", Anne Arundel Medical Center, Annapolis, MD 9/22/97.

"Laparoscopic and Vaginal Anatomy", course prosector and faculty member, Society of Pelvic Reconstructive Surgeons, Philadelphia, PA 2/5-6/98.

"Vaginal Vault Prolapse", St. Joseph Hospital Grand Rounds, Baltimore, MD 3/12/98.

"Laparoscopic and Vaginal Anatomy", course prosector and faculty member, Society of Pelvic Reconstructive Surgeons, Philadelphia, PA 4/23-24/98.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Philadelphia, PA 1/14-15/99.

"Surgical Management of Stress Incontinence", course prosector and faculty member, Innovations in Medical Education and Training (IMET), San Diego, CA 2/10-13/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Savannah, GA 3/11-13/99.

"Urinary Incontinence", Women's Health Self-Health series, Center of Excellence in Women's Health, UMMS, 8/18/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Pomona, CA 9/16-18/99.

"Dysuria Syndromes and Interstitial Cystitis", Johns Hopkins Health System, 11/16/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Savannah, GA 3/10-11/2000.

"Incontinence in Women", Baltimore Veteran's Administration, Baltimore, MD, 5/8/2000.

"Advanced Laparoscopic Reparative Pelvic Surgery & Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Las Vegas, NV 9/15-9/16/2000.

"Pelvic Floor Dysfunction in Women", program Co-director and faculty member, Innovations in Medical Education and Training (IMET), Baltimore, MD 5/10-5/12/2001.

"Treatment of Stress Urinary Incontinence", York Hospital, York, PA, 5/19/2010.

"Pelvic Anatomy", "Mesh Complications", (Pelvic Support Workshop & Seminar), St. Agnes Medical Center, Catonsville, MD 3/2/2012-3/3/2012.

"Pelvic Organ Prolapse", St. Joseph Medical Center, Towson, MD, 6/13/2013.

Exhibit C

Prior Testimony

In the past four years, I have testified in the following cases:

- 11/6/13, Richardson v Miller deposition
- 8/28/13, Woods v Cossell deposition
- 3/20/13, Rodriguez v Rao deposition
- 2014, Fleming v. Pleeter
- 2014, Stidham
- 2015, Streaker v. Boushehri
- 2015, Ehrsam v. Hopkins
- 2015, Harris v. McMillan
- 2016, Powers v. Harrison
- 4/29/16, Riggs v. Ethicon
- 6/21/16, Bihlmeyer v. Ethicon
- 7/14/16, General deposition (Consolidated Litigation)
- 7/15/16, Bennett v. Ethicon
- 7/13/16, Garcia v. Ethicon
- 7/13/16, Martinez v. Ethicon
- 7/15/16, Mullens v. Ethicon
- 7/13/16, Tomblin v. Ethicon
- 7/14/16, Webb v. Ethicon
- 9/1/16, Onal v. University of Maryland
- 11/18/16, Chase v. Ethicon
- 2/9/17, Powers v. Harrison

HARRY WALLACE JOHNSON, JR., M.D.
Curriculum Vitae

ADDRESS: University of Maryland School of Medicine
Department of Obstetrics, Gynecology and
Reproductive Sciences
[redacted]

Telephone: [redacted]
Fax: [redacted]
Email: [redacted]

PERSONAL INFORMATION:

Born: [redacted]
Citizenship: USA
Martial Status: [redacted].
Children: [redacted]

EDUCATION:

Undergraduate:	1978	Duke University B.A. - Management Science
	1980	University of North Carolina at Greensboro B.A. - Biology Honors - Beta Beta Beta Biology National Honor Society
Medical:	1984	Wake Forest University Medical Center Bowman Gray School of Medicine - M.D.
Postgraduate:	1984-85	Wake Forest University Medical Center North Carolina Baptist Hospitals, Inc. Internship - General Surgery
	1985-89	University of Maryland Medical Center Department Obstetrics and Gynecology
	1985-86	Internship
	1986-87	Junior Assistant Resident
	1987-88	Senior Assistant Resident
	1988-89	Administrative Chief Resident
	1992-93	Fellowship - Greater Baltimore Medical Center Pelvic Surgery, Operative Endoscopy, Urogynecology

LICENSURE:

Maryland State Board of Medical Examiners (1989-Present)
FLEX

SPECIALTY BOARDS:

Diplomate, American Board of OB-GYN (12/13/1991)
Recertification- 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013.

PROFESSIONAL MEMBERSHIP:

American College of Obstetricians and Gynecologists Fellow
American Association of Gynecologic Laparoscopists
American Urogynecology Society
Association of Professors in Gynecology and Obstetrics
International Urogynecological Society
Society of Pelvic Reconstructive Surgeons
Fellow American College of Surgeons
Medical and Chirurgical Faculty of Maryland
Maryland OB/GYN Society
Baltimore City Medical Society
Douglass Obstetrical and Gynecology Society

CERTIFICATIONS:

Basic Life Support
Advanced Trauma Life Support
Armed Forces War Surgery/Skills Enhancement

MILITARY SERVICE:

United States Navy (1989-1992)
LCDR. USNR - MC
National Naval Medical Center, Bethesda, MD

MILITARY AWARDS (U.S. NAVY):

Navy Unit Commendation Medal
Meritorious Unit Commendation
Navy Commendation Medal
South West Asia Campaign Medal with 2 Bronze Stars
National Defense Medal
Sea Service Award
Kuwait Liberation Medal

ACADEMIC POSITIONS:

University of Maryland, School of Medicine
Associate Professor, Department of Surgery, Division of Urology (2010-present)
Head, Division of Urogynecology and Pelvic Reproduction (2003-present)
Associate Vice Chairman (2003-present)
Associate Professor (1999-present)
Assistant Professor (1995-1999)
Clinical Instructor (1992-1995)
Director OB-GYN Residency Training Program (1993-2004)

Uniformed Services University of the Health Sciences
F. Edward Herbert School of Medicine
Clinical Instructor (1989-1991)
Assistant Professor (1991- 1992)

CURRENT MAJOR RESPONSIBILITIES:

1. Associate Vice Chairman
   Department of Ob/Gyn and Reproductive Sciences
   University of Maryland Medical System
2. Associate Professor
   Head, Division of Urogynecology, Pelvic Reconstructive Surgery
   University of Maryland Medical System
3. Director of Gynecology
   Baltimore V.A. Medical Center
4. Consultant - Urogynecology and Endoscopic Surgery
   Mercy Medical Center

PROFESSIONAL AWARDS:

OB-GYN Department Teacher of the Year Award (1994)
Baltimore's Best Doctor listing, ***Baltimore Magazine*** (1995, 1997, 2002, 2004, 2006, 2008, 2009, 2010, 2011, 2013)
The Best Doctors in America: Southeast Region (1996)
Audiovisual "Laparoscopic Pelvic Anatomy", ACOG second prize (1996)
APGO Excellence in Teaching Award (1996)
Best Doctors in America (2003-present)
Guide to America's Top Obstetricians and Gynecologists listing (2006 Edition- present)

HOSPITAL MEDICAL STAFF APPOINTMENTS:

2010-Present	Attending Staff, Upper Chesapeake Medical Center, Bel Air, MD
2010-Present	Attending Staff, Baltimore Washington Medical Center, Glen Burnie, MD
2004-2012	Attending Staff, St. Joseph Medical Center, Towson, MD
1992-Present	Attending Staff, University of Maryland Hospital, Baltimore, MD
1992-Present	Attending Staff, Mercy Medical Center, Baltimore, MD
1992-2011	Attending Staff, Greater Baltimore Medical Center, Towson, MD
1996-Present	Attending Staff, VA Medical Health Care System, Baltimore, MD
1991-1994	Associate Staff, St. Agnes Hospital, Baltimore, MD
1991-1994	Associate Staff, Prince George's Hospital, Cheverly, MD
1989-1992	Attending Staff, National Naval Medical Center, Bethesda, MD (Director of Ambulatory Care, Director of Urodynamic Testing Center)
1989-1992	Attending Staff, Naval Hospital, Patuxent River, MD
1989-1990	Attending Staff, Naval Hospital, Yakoska, Japan
1990-1991	Head Division OB-GYN, USNS Comfort Hospital Ship

ACADEMIC HOSPITAL COMMITTEES:

National Naval Medical Center, Committee for the protection of Human Subjects (1989-1992)

University of Maryland Medical System:

UMMC Credentials Committee (1993-present)
UM School of Medicine Faculty Senate (1993-1994)
UM School of Medicine Longitudinal Ambulatory Committee (1993-1997)
UM School of Medicine Graduate Medical Education Committee (1994-1996)
UM School of Medicine Graduate Medical Education Committee Chair (1996-2002)
UM School of Medicine Graduate Medical Education Policy Committee (1996-2002)

COMMITTEES: University of Maryland Medical System (continued)

UMMC Medical Executive Committee (1996-present)
UMMC Women's Services Oversight Group (1996-present)
UMMC Administrative Affairs Committee (1997-present)
UMMC Operating Room Committee (1997-2009)
University of Maryland Obstetrical and Gynecological Associates, P.A.
Member, Board of Directors (1996-present)
Vice President (1996-present)
UMMC Chief Resident Forum (1998-2000)
UMMC Performance Improvement Steering Committee (1999-present)
UMMC Institutional Advancement/Outreach Subcommittee (2000-2001)

Mercy Medical Center:

Physician Leadership Group for the Women's Center (1995-1998)
OB-GYN Residency Steering Committee (1997-2004)

SUPERVISORY EXPERIENCE:

Fellows:

Urogynecology, Pelvic Reconstructive Surgery Fellow
Barbara Plucknett, MD, 1996
Paul Marshburn, MD, 1996
Aileen Yee, MD, 1997
Salil Khandawala, MD, 1997
Kio Nihira, MD, 1998
Mark Ellerkman, MD, 1999
Jerome Buller, MD, 2000
Nga Turner, MD, 2000
Kenneth Leffler, MD, 2001
James Dunn, MD, 2001
Joan Bloomquest, MD, 2001
Andrew McBride, MD, 2002
Janet Li, MD, 2003
Matthew Fagan, MD, 2004
Danita Akingba, MD, 2005
Folusho Tugbiyele, MD, 2006
Tatiana V. Sanses, MD, 2007
Kay A. Hoskey, MD, 2008

Maria D. Hernandez, MD, 2009
Toni R. Slyvester, MD, 2011

Residents

1993 – 2004 Director of Department of Obstetrics, Gynecology and Reproductive Sciences Residency Training Program

1993 - present Faculty Attending (one week/month)
Gynecology Service, University of Maryland Medical Center

1993 - 2004 OB/GYN Morbidity Mortality Conference (weekly)

4/97 & 4/98 Baltimore/Washington Ethics Retreat, Group facilitator

Medical Students

1993 - 2005 Core Lecturer, Clinical Care Rotation in Obstetrics and Gynecology, University of Maryland School of Medicine, (2-3 lectures every six weeks)

1990 -present Preceptor, Third year Clinical Care Rotation, Obstetrics and Gynecology, University of Maryland School of Medicine

1993 - 2005 Course Master - Fourth Year Elective Rotation, Gynecologic Surgery

1993 - 2005 Physical Diagnosis Course to Sophomore Students (Breast Exams)

RESEARCH GRANTS:

1. Urinary Incontinence Treatment Network: Continence Treatment Centers
   Co-PI, 7/1/01 to 6/30/05
   Grant: DK-01-018
   Grant: HD-00-013
   Direct Costs: $857,904

2. Effects of Stretch on IC and Normal Urothelia
   Co-investigator, 6/1/01 to 5/31/06
   Grant R01-DK59441-01

3. Race, Lipoprotein Lipase and Obesity after Menopause
   Co-Investigator, 4/1/03 to 3/31/09
   Grant R01-AG20116 NIH/NIA
   $2,276,038

4. Gynecology Services for Female Veterans, Veterans Administration Medical Center
   Principal Investigator, 1996-present
   Direct Costs: $80,504

PUBLICATIONS:

Perdue,PW, Johnson,Jr.,HW, Stafford,PW. Intestinal Obstruction Complicating Pregnancy. The American Journal of Surgery. 1992;104:384-88.

Chai,TC, Zhang,CO, Shoenfelt,JL, Johnson,Jr.,HW, Warren,JW, Keay,S. Bladder Stretch Alters Urinary Heparin-Binding Epidermal Growth Factor and Antiproliferative Factor in Patients with Interstitial Cystitis. The Journal of Urology. 2000;163:1440-44.

Richter,HE, Burgio,KL, Brubaker,L, Moalli,PA, Markland,AD, Mallet,V, Menefee,SA, Johnson,HW, Boreham,MK, Dandreo,KJ, Stoddard,AM. Factors associated with incontinence frequency in a surgical cohort of stress incontinent women. Am J Obstet Gynecol, 2005;193:2088-93.

Urinary Incontinence Treatment Network. Design of the stress incontinence surgical treatment efficacy trial (SISTEr). Urology, 2005;66:1213-17.

Urinary Incontinence Treatment Network. Design of the Behavior Enhances Drug Reduction of Incontinence (BE-DRI) study. Contemp Clin Trials. 2007 Jan; 28(1): 48-58.

Albo,ME, Richter,HE, Brubaker,L, Norton,P, Kraus,SR, Zimmern,PE, Chai,TC, Zyczynski,H, Diokno,AC, Tennstedt,S, Nager,C, Lloyd,LK, FitzGerald,MP, Lemack.GE, Johnson,HW, Leng,W, Mallett,V, Stoddard,AM, Menefee,S, Varner,RE, Kenton,K, Moalli,P, Sirls,L, Dandreo,KJ, Kusek,JW, Nyberg,LM, Steers,W. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med, 2007;356:2143-55.

Burgio,KL, Kraus, SR, Menefee, S, Borello-France, D, Corton, M, Johnson, HW, Mallet, V, Norton, P, FitzGerald, MP, Dandreo, K, Richter, H, Rozanski, T, Albo, M, Zyczynski, HM, Lemack, GE, Chai, TC, Khandwala, S, Baker, J, Brubaker, L, Stoddard, AM, Goode, PS, Nielsen-Omeis, B, Nager, C, Kenton, K, Tennstedt, SL, Kusek, JW, Chang, D, Nyberg, LM, Steers, W. Behavioral Therapy to Enable Women with Urge Incontinence to Discontinue Drug Treatment. Ann Intern Med, 2008 Aug 5;149(3): 161-9.

Urinary Incontinence Treatment Network. The Trial Of Mid-Urethral Slings (TOMUS): Design and Methodology. J Applied Res. 2008 Jan, 8:1-13.

Brubaker,L, Stoddard,A, Richter,H, Zimmern,P, Moalli,P, Kraus,SR, Norton,P, Lukacz,E, Sirls,L, Johnson,HW. Mixed Incontinence: Comparing Definitions in Women Having Stress Incontinence Surgery. Neurourol Urodynam, 2009 April; 28(4): 268-73.

Brubaker,L, Richter,H, Tennstedt,SL, Wai, Menefee,S, Borello-France, Johnson,HW, Kraus,SR, Sirls,L. Patient Satisfaction with Stress Incontinence Surgery. Neurourol Urodyn. 2010; Nov; 29 (8): 1403-9.

FitzGerald, Johnson,HW, Kraus,SR, Lemack,GE, Mallett,V, Stoddard, Tennstedt,SL, Zyczynski. Patient Expectations and Their Relationship to Baseline Symptoms, Patient Locus of Control and Outcomes. Submitted ICS, 2009.

Richter,HE, Albo,ME, Zyczynski,HM, Kenton,K, Norton,PA, Sirls,LT, Kraus,SR, Chai,TC, Lemack,GE, Dandreo,KJ, Varner,RE, MenefeeS, GhettiC, Brubaker,L, Nygaard,I, Khandwala,S, Rozanski,TA, Johnson,H, Schaffer,J, Stoddard,AM, Holley,RL, Nager,CW, Moalli,P, Mueller,E, Arisco,AM, Corton,M, Tennstedt,S, Chang,TD, Gormley,EA, Litman,HJ. Retropubic versus Transobturator Midurethral Slings for Stress Incontinence. N Engl J Med, 2010 Jun 3; 362(22): 2066-76.

Brubaker,L, Lukacz,ES, Burgio,K, Zimmern,P, Norton,P, Leng,W, Johnson,H, Kraus,S, Stoddard,A. Mixed Incontinence: Comparing Definitions in Non-Surgical Patients. Neurourol Urodyn, 2011 Jan; 30(1): 47-51.

Nager,CW, Brubaker,L, Litman,HJ, Zyczynski,HM, Varner,RE, Amundsen,C, Sirls,LT, Norton,PA, Arisco,AM, Chai,TC, Zimmern,P, Barber,MD, Dandreo,KJ, Menefee,SA, Kenton,K, Lowder,J, Richter,HE, Khandwala,S, Nygaard,I, Kraus,SR, Johnson,HW, Lemack,GE, Mihova,M, Albo,ME, Mueller,E, Sutkin,G, Wilson,TS, Hsu,Y, Rozanski,TA, Rickey,LM, Rahn,D, Tennstedt,S, Kusek,JW, Gormley,EA. A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery. N Engl J Med, 1012 May 24;-366(21): 1987-97.

ABSTRACTS:

Johnson,Jr.,HW. Laparoscopic Burch Colposuspension in Fresh Cadavers. American Urogynecologic Society, New Orleans, LA. 1996.

Johnson,Jr.,HW, Bent,AE, Rogers,Jr.,RM, McLennan,M, Plucknett,B. Laparoscopic Retroperitoneal Anatomy Using Fresh Cadavers. American College of Obstetrics and Gynecology, District IV, Lake Buena Vista, FL. 1996.

Johnson,Jr.,HW, Bent,AE, Rogers,Jr.,RM, McLennan,M, Plucknett,B. Laparoscopic Dissection of the Female Pelvis using Fresh Female Cadavers. American Urogynecologic Society, New Orleans, LA. 1996.

Johnson,Jr.,HW, Bent,AE, Rogers,Jr.,RM, McLennan,M, Plucknett,B. Laparoscopic Anatomy: A Correlative Examination of Pelvic Anatomy in Fresh Cadavers and Live Operative Procedures. American Urogynecologic Society, New Orleans, LA. 1996.

Howell, Jesse, Johnson,HW, Sirls,L, Dandreo,K, Gruss, Hall. Learning from the SISTEr trial: findings from the Patient Burden Survey at study completion. Oral Poster, ICS, 2009.

AUDIOVISUALS:

Laparoscopic Pelvic Anatomy. 1996 (Awarded 2nd prize by ACOG)

INVITED SPEECHES/PRESENTATIONS:

"Benign Conditions of the Ovary & Fallopian Tube", resident/faculty seminar 3/16/94

"Complications in Endoscopic Surgery", St. Joseph Hospital Grand Rounds, OB-GYN Dept., Baltimore, MD 6/2/95

"Urinary Incontinence" and "Advances in Laparoscopic Surgery" , Advances in Health Care for Women Over 40, Wash, DC 6/17/94

"Dysfunctional Uterine Bleeding", 20th Annual Family Medicine Review Course, Ocean City, MD 6/21/94
"Techniques to Decrease Surgical Morbidity", 13th Annual Update in Obstetrics & Gynecology, Annapolis, Maryland 6/23/94

"Urinary Incontinence", University of Maryland Hospital, Women's Health Month, Baltimore, MD 9/23/94

Urogynecology", Mercy Medical Center Grand Rounds, OB-GYN Dept., Baltimore, MD 11/3/94

"Vaginal Vault Prolapse", St. Joseph Hospital Grand Rounds, Baltimore, MD 12/1/94

"Vaginal Prolapse", Mercy Medical Center Grand Rounds, OB-GYN Dept., Baltimore, MD 2/8/95
"Pelvic Floor Reconstruction", University of Maryland Hospital Grand Rounds, Urology Dept., Baltimore, MD 5/11/95

"Vaginal Vault Prolapse", Anne Arundel Medical Center, Annapolis, MD 5/25/95

"Vaginal Hysterectomy (Laparoscopic Assisted)", Controversies in GYN: Medical & Surgical Management of Uterine Fibroids, Washington DC 6/3/95

"Vaginal Vault Prolapse", University of Maryland Hospital Grand Rounds, OB-GYN Department, Baltimore, MD 6/23/95

"How to Approach the Patient in Menopause:, Perry Point VA Hospital, MD 9/12/95

"Abnormal Uterine Bleeding", Sheraton Inner Harbor, Dept. CME Course, Baltimore, MD 9/29/95

"Ureteral Injury in Gynecologic Surgery", St. Joseph Hospital Grand Rounds, Baltimore, MD 12/7/95

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“Laparoscopic and Vaginal Anatomy”, course prosector and faculty member, Society of Pelvic Reconstructive Surgeons, Philadelphia, PA 2/5-6/98.

“Vaginal Vault Prolapse”, St. Joseph Hospital Grand Rounds, Baltimore, MD 3/12/98.

“Laparoscopic and Vaginal Anatomy”, course prosector and faculty member, Society of Pelvic Reconstructive Surgeons, Philadelphia, PA 4/23-24/98.

“Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers”, course prosector and faculty member, Innovations in Medical Education and Training (IMET), Philadelphia, PA 1/14-15/99.

"Surgical Management of Stress Incontinence", course prosector and faculty member, Innovations in Medical Education and Training (IMET), San Diego, CA 2/10-13/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Savannah, GA 3/11-13/99.

"Urinary Incontinence", Women's Health Self-Health series, Center of Excellence in Women's Health, UMMS, 8/18/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Pomona, CA 9/16-18/99.

"Dysuria Syndromes and Interstitial Cystitis", Johns Hopkins Health System, 11/16/99.

"Reparative Pelvic Surgery and Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Savannah, GA 3/10-11/2000.

"Incontinence in Women", Baltimore Veteran's Administration, Baltimore, MD, 5/8/2000.

"Advanced Laparoscopic Reparative Pelvic Surgery & Surgical Dissection on Unembalmed Female Cadavers", course prosector and faculty member, Innovations in Medical Education and Training (IMET), Las Vegas, NV 9/15-9/16/2000.

"Pelvic Floor Dysfunction in Women", program Co-director and faculty member, Innovations in Medical Education and Training (IMET), Baltimore, MD 5/10-5/12/2001.

Harry Johnson

General Reliance List
in Addition to Materials Referenced in Report

MDL Wave 4

Harry Johnson Reliance List

Medical Literature

Abdel-Fattah M, Barrington JW, Arunkalaivanan AS. Pelvicol pubovaginal sling versus tension free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. Eur Urol 2004;46:629-35.
Abdel-fattah M, et al. (NHS Scotland) Primary and repeat surgical treatment for female pelvic organ prolapse and incontinence in parous women in the UK: a register linkage study. BMJ (2011)
Abdel-Fattah M, et al. Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse. BJOG (2008) 115: 22-30.Urogynecol j 22: 789-798.
Abdel-Fattah M, Familusi A, Ramsay I, N'Dow J. A randomised prospective single-blinded study comparing inside-out versus outside-in transobturator tapes in the management of female stress urinary incontinence (E-TOT study): 3 years follow-up. Neurourol Urodyn 2011;30:825-826.
Abdel-fattah M. Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes. European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111
Abdel-fattah M. How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. BJU International 98, 594-598
Abdel-fattah M. Lower urinary tract injuries after transobturator tape insertion by different routes: a large retrospective study. BJOG 2006;113:1377-1381.
Abdel-fattah M. Prospective Randomised Controlled Trial of Transobturator Tapes in management of Urodynamic Stress Incontinence in Women: 3-Year Outcomes from the Evaluation of Transobturator Tapes Study. EUROPEAN UROLOGY 62 (2012) 843-851
Abdel-fattah M. Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study. BJOG 2010;117:870-878.
Abdel-Fattah M. Single-Incision Mini-Slings versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontincen: A Meta-Analysis of Effectiveness and Complications. EUROPEAN UROLOGY 60 (2011) 468-480
Abdelmonem A. Vaginal length and incidence of dyspareunia after total abdominal versus vaginal hysterectomy. European Journal of Obstetrics & Gynecology and Reporductive Biology 151; 2010; 190-192
Abdelwahab O. Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence. Curr Urol 2010;4:93-98
Abduljabbar H. Comparison of the classic TVT and TVT Secur. Prime Research on Education ISSN: 2251-1253. Vol. 2(9), pp. 344-347, October 31st, 2012
Abed H. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J; 2011;11:1384-95.
Adhoute F, et al. Use of transvaginal polypropylene mesh (Gynemesh) for the treatment of pelvic floor disorders in women. Prospective study in 52 patients. Prog Urol 2004;14(2):196-196.
Adile B, Granese R, Lo Bue A, GuglioOtta G, Cardella AM, Adile C. A prospective randomized study comparing laparoscopic Burch versus TVT: short and long term follow-up. ICS 2003:Abstract 550.
Agarwala N. A randomized comparison of two synthetic mid-urethral tension-free slings. Uro Today Int J 2008 Oct;1(4) doi:l0.3834/uij. 1939-4810.2008.10.5.
Agostini A, et al. [Pop 12,280] Immediate complications of tension-free vaginal tape (TVT): results of a French survey. Eur J Obstet Gynecol. 2006; 124:237-239.
Aigmueller T, et al. [10 yr fu] Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol. 2011; 205:496.e1-5.
Aigmueller T. Reasons for dissatisfaction ten years after TVT Procedure. Int Urogynecol J (2014) 25:213-217.

Harry Johnson Reliance List

Medical Literature

Albo M, Richter, Zimmern, Moalli, Sirls. - NEJM - SISTEr study - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med 2007;356:2143-55.
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Document Description [Bates Range]
10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture
2005-06 Prof Ed Slides _ Exhibit 127
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2007 Prolift Professional Education Slide Deck
2007 Prolift Surgeon's Resource Monograph
2007 Prolift Surgical Technique Guide
2008 Prolift Patient Brochure
2011 Pelvic Organ Prolapse and Stress Urinary Incontinence Patient Counseling Guide
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse by V. Lucente, et al. 1 pg.
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2005 (8 pgs)
Brochure Treatment Options for Pelvic Organ Prolapse Stop coping. Start living. Dated in 2008 Gynecare Prolift (15 pgs)
Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.
D00000019
D00000730
D00001256-2005 Prolift Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems) [Native Format]
D00001260-2007 and 2008 Prolift and M Prof Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems)[Native Format]
DEFT 730.1-730.72 - 2007 Prolift Surgeons Monograph
DEPO.ETH.MESH.00004755 - Guidoin Explant
Deposition Subject Matter-Design and Development of Mesh Products
Device Labeling Guidance
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH.MESH.00020763 - Prolift +M Profession Education Slide Deck
ETH.MESH.00020764 - Prolift +M Profession Education Slide Deck
ETH.MESH.0003132 - Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift
ETH.MESH.00031323
ETH.MESH.00031324-25 - Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00093526-44 - Prolift +M Profession Education Slide Deck
ETH.MESH.00093991 - Prolift +M Profession Education Slide Deck

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ETH.MESH.00161953-54
ETH.MESH.00167104-10 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00222852-63
ETH.MESH.00222899-909
ETH.MESH.00223779-84
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00262089-123
ETH.MESH.00295355 - 2010 TVT Exact Prof Ed
ETH.MESH.00341006-11
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00369995 - 2008 TVT Family of Products
ETH.MESH.00371496-594
ETH.MESH.00372564-68 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number 2003-016
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
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ETH.MESH.00442825-26
ETH.MESH.00484929 - 2005-2006 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation cover sheet
ETH.MESH.00524746-48
ETH.MESH.00525573
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00575257 - Abbrevo laser cut vs. mechanically cut - notes from meeting with de leval – inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00584811-13 - Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00658177-98
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00823793-806
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03

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ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860239-310 - TVT-O IFU
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00865069-72
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00870466-76 - 6.2.2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair
ETH.MESH.00991195-257 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number CT-TVM-001-03
ETH.MESH.00993273 - 2006 TVT-O Summit Presentation by Raders and Lucente
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01075187-215 - Clinical Expert Report Gynecare Prolift Pelvic Floor Repair System dated 7.2.10
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01210987-95
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01222075-079
ETH.MESH.01222075-79
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01310817-29 - Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvice Floor Repair System dated 1.19.05
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01320328-33 - Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
ETH.MESH.01320351-67- Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006
ETH.MESH.01595614-753 - Prolift +M IFU
ETH.MESH.01612323-33 - Patient Brochure: Pelvic Organ Prolapse "Get the Facts, Be Informed, Make Your Best Decision."
ETH.MESH.01751069-94
ETH.MESH.01752532-35 - Mesh design argumentation issues
ETH.MESH.01784779-82
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email string re: +M relaxation
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809056-58
ETH.MESH.01809080-81
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01815660-64

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ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.02001398-473 - Prolift IFU
ETH.MESH.02017152-56 – 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
ETH.MESH.02017152-58
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02105765-71 - Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08
ETH.MESH.02211890 - Test Report
ETH.MESH.02219584 - Scion PA-SUI Treatment Unmet Needs Exploratory Research
ETH.MESH.02229063 - Secur placement
ETH.MESH.02232773-801 - Prolift +M Profession Education Slide Deck
ETH.MESH.02232854-74 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233126-187 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233290 - Prolift +M Profession Education Slide Deck
ETH.MESH.02236604-09
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
ETH.MESH.02270857-858 - Owens 2012-09-13 3005 - Jacquetin high erosion rate with Vypro
ETH.MESH.02293715-6
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02330766 - TVT-O (Reproducible Vaginal Approach) (TVTO-384-10-8-12)Production 36_000124_4580875_d
ETH.MESH.02340306-69 - TVT IFU
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340471-503 - TVT IFU
ETH.MESH.02340504
ETH.MESH.02340504-67 - TVT IFU
ETH.MESH.02340529-533
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340756-828 - TVT-O IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02340829-901 - TVT-O IFU
ETH.MESH.02340902-08
ETH.MESH.02340902-73 - TVT-O IFU
ETH.MESH.02340974-1046 - TVT-O IFU
ETH.MESH.02341203-13 - TVT Abbrevo IFU
ETH.MESH.02341454-521 - Prolift IFU
ETH.MESH.02341522-27 - 2005 Prolift IFU
ETH.MESH.02341522-89 - Prolift IFU
ETH.MESH.02341658-733 - Prolift IFU
ETH.MESH.02341734-809 - Prolift IFU
ETH.MESH.02614610-24 - Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

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ETH.MESH.02615519-658 - Prolift +M IFU
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03364663-66
ETH.MESH.03365250-1
ETH.MESH.03427878-83
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to11.26.14)
ETH.MESH.03427878-946 - TVT IFU
ETH.MESH.03458123-38 - Patient Brochure
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03459088-104 - Patient Brochure
ETH.MESH.03667696-704 – Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices
ETH.MESH.03715978 - Weisberg email re: TVT question.
ETH.MESH.03736120-27 - Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03751819 - 2009 The Science of What's Left Behind
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905968-75 - 2005 Prolift Patient Brochure
ETH.MESH.03905976-91 - Patient Brochure
ETH.MESH.03905992-6000 - Patient Brochure
ETH.MESH.03906001-20 - Prolift +M Patient Brochure
ETH.MESH.03906037-52 - Patient Brochure
ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03922926-28
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-11
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03932912-14 - The History of TVT
ETH.MESH.03934952-67
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04048515-20
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04094863-864
ETH.MESH.04181761-62 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile

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ETH.MESH.04384126-65
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevo
ETH.MESH.04939001
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05222673-705 - TVT IFU
ETH.MESH.05225354-85 - TVT IFU
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05315252-65
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05701011-1058
ETH.MESH.05795421-508 - 2001 slides from Parisi binder
ETH.MESH.05795537-99 - 1998 TVT Slide Deck
ETH.MESH.05799233-316 - TVT-E IFU
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06049894-96 - FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11
ETH.MESH.06087471-2 - Patient Brochure
ETH.MESH.06087513-4 - Patient Brochure
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06696411-19
ETH.MESH.06859834-35
ETH.MESH.06878438-39
ETH.MESH.06882641-2
ETH.MESH.06886410-11
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 – 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07246690-719 - Study Report dated May 8, 2012: A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.07351297 - Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>

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ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07393700
ETH.MESH.07692905-7
ETH.MESH.07937826-828
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003247-62 - Patient Brochure
ETH.MESH.08003263-78 - Patient Brochure
ETH.MESH.08003279-94 - Patient Brochure
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-301
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08003303-17
ETH.MESH.08107354 - Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides
ETH.MESH.08117473 - 2012 TVT-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08117625-26 - Prolift +M Profession Education Slide Deck
ETH.MESH.08156958 - 2002 TVT Advanced Users Forum Presentation
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-45 - Email from Hinoul re: RCTs to 11/2012 on TVT-O and TVT with Excel attachment
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08334244; ETH.MESH.08334245 - Email re Photographs of LCM vs MCM with attachments
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.09100506 - 2005 Prolift Profession Educational Slide Deck
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09281461 - TVT-Abbrevo - a modified version of TVT-O 2010
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744840-45 - Patient Brochure
ETH.MESH.09744848-55 - Patient Brochure
ETH.MESH.09744858-63 - Patient Brochure
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10027307-28 - TVT Surgeons Resource Monograph - June 2000
ETH.MESH.10220659 - Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
ETH.MESH.10281860 - 2013 Clinical Expertise TVT Prof Ed Slide Deck
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.

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ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111
ETH.MESH.1210987-95 - Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal
ETH.MESH.1222075-79 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer
ETH.MESH.12831391-92 - P4128 – IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.161953-54 - 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture Gynecare TVT Obturator System Sales Materials
ETH.MESH.1751069-94 - 09/07/2009 Safety review: TVT and TVT-O procedures
ETH.MESH.1784779-82 - Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis
ETH.MESH.1809056-58 - Email re: Important Laser cut mesh update
ETH.MESH.1809080-81 - Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641)
ETH.MESH.1815660-64 - Project Mulberry, Preliminary Clinical Diligence Report
ETH.MESH.22129031-37
ETH.MESH.222852-63 - 12/15/2003, Gynecare Final Report # 03*0740, TVT Obturator System
ETH.MESH.222899-909 - Clinical Expert Report
ETH.MESH.2236604-09 - TVT Obturator Brochure; “Results, Precision & Proven Mesh”
ETH.MESH.223779-84 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3
ETH.MESH.2293715-16 - Email from Dan Smith re: NG TVT-O NDP – Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny
ETH.MESH.2340504-33 - TVT IFU
ETH.MESH.2340902-08 - TVT O IFU
ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out
ETH.MESH.3364663-66 - Email from O’Bryan re: ifu
ETH.MESH.3365250-51 - Email from Weisberg re: IFU update
ETH.MESH.341006-11 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1)
ETH.MESH.3427878-83 - TVT IFU
ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TVT System
ETH.MESH.3911390-91 - Email from Arnaud re: Transient Leg Pain with Mulberry
ETH.MESH.3922926-28 - Email re: OR Agenda Tunn
ETH.MESH.3932909-11 - History of TVT-O
ETH.MESH.3934952-67 - Tension-Free Vaginal Obturator Tape (TVOT) – April 30, 2003 – Meeting Report
ETH.MESH.3939167-71 - Waltregny (2006) Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup
ETH.MESH.4048515-20 - KOL Interview
ETH.MESH.4384126-65 - Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide
ETH.MESH.442825-26 - Email re: TVT Laser Mesh info

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ETH.MESH.52235354-85
ETH.MESH.524746-48 - Email re: TVT Meeting with Agency
ETH.MESH.525573 - Email re: TVT Laser Cut Mesh
ETH.MESH.5315252-65 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.658177-98 - TVT Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting
ETH.MESH.6696411-19 - Email re: Performance Evaluation of TVT Prolene Blue Mesh
ETH.MESH.6859834-35 - Email re: Laser Cut TVT
ETH.MESH.6878438-39 - Memo re: VOC on new Laser Cut TVT Mesh
ETH.MESH.6882641-42 - Email from O'Bryan re: GYNECARE TVT Obturator System – FDA
ETH.MESH.6886410-11 - Email from Weisberg re: Mulberry
ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy
ETH.MESH.7692905-07 - Email re: Mesh Fraying Dr. EBERHARD letter
ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living."
ETH.MESH.8003303-17 - Patient Brochure: "Stop coping, start living."
ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical Experience
ETH.MESH.865069-72 - Email from Dan Smith re: Draft report translated by "Babel fish" http://babelfish.altavista.com/tr
ETH.MESH.PM.000001 - Prolift Professional Education Videos
ETH.MESH.PM.000002 - TVT-O Procedural Video
ETH.MESH.PM.000006 - Anatomy Videos
ETH.MESH.PM.000007 - Prolift Professional Education Videos
ETH.MESH.PM.000009 - Anatomy Videos
ETH.MESH.PM.000014 - Prolift Professional Education Videos
ETH.MESH.PM.000015 - Prolift Professional Education Videos
ETH.MESH.PM.000019 - Prolift Professional Education Videos
ETH.MESH.PM.000027 - Prolift Professional Education Videos
ETH.MESH.PM.000032 - Prolift Professional Education Videos
ETH.MESH.PM.000033 - Prolift Professional Education Videos
ETH.MESH.PM.000034 - Prolift +M Professional Education Videos
ETH.MESH.PM.000037 - Prolift Professional Education Videos
ETH.MESH.PM.000038 - Prolift Professional Education Videos
ETH.MESH.PM.000039 - Prolift Professional Education Videos
ETH.MESH.PM.000048 - Prolift +M Professional Education Videos
ETH.MESH.PM.000057 - Anatomy Videos
ETH.MESH.PM.000058 - Prolift Professional Education Videos
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068 - Anatomy Videos
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos

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ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000179 - TVT Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TVT-Secur Key Tech Points 5.24.2007 (Color Oringinal from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
ETH_10437 - Gynemesh PS IFU
ETH-00254-61 - Patient Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2006
ETH-00295-300 - Exh. 10 Gynecare Prolift IFU dated 2004
ETH-01363-65 - Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512
ETH-02387 - Lucente V. Prospective Clinical Assessment Of The Total Vaginal Mesh (TVM) Technique For Treatment Of Pelvic Organ Prolapse - 6 And 12 Month Results
ETH-07252-81 - Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique
ETH-0977 - 2009 Prolift IFU
ETH-10505-96 - 2008 Prolift Slide deck
ETH-10977-83 - Gynecare Prolift IFU dated 2009
ETH-18415 - Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Exh 59 - Gynecare Prolift Pelvic Floor Repair System Physcian Learner Profile (2 pages)
Exh 59 - Materials sent to Kaminski for review 01-30-2012
Exhibit 127 - Gynecare prolift pelvic floor repair slides (page 1-30)
Exhibit 128 - Gynecare prolift pelvic floor repair slides
Exhibit 59 - Gynecare prolift pelvic floor repair system continnum of education
Get the facts, be informed, make your best decision – (Defense 824)
Gynecare Prolift Pelvic Floor Repair System Surgical Technique Guide
Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides
Gynecology Solutions
HMESH.ETH.11642462 – Franchise Regulatory Labeling Guidence
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
Librojo updated TVT Declaration (10-23-15) [12 pages]
May 15, 2008 510(K) Summary of Safety and Effectiveness
McCabe email re - Sheath Sales Tool - 464
Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT
MSDS-Marlex Polypropylenes

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Production Materials

P4122 – SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
PowerPoint Mechanical vs. “Machine”-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer
Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
Summary of Safety and Effectiveness submitted by Bryan Lisa for Gynecare Prolift and Prolift +M stamped 5.15.08 (2 pgs) – FOUND
Summary of TVT-O Long-Term Studies
Surgeon's Rescourse Monograph for TVT
TVT & TVT-O Long Term Studies - No Confidential Stamp
TVT Abbrevo IFU – 01.2015
TVT Exact IFU – 01.2015
TVT IFU – 01.2015
TVT Patient Brochure - 2015
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator – 01.2015
TVT-R Prof Education Slide Deck

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Company Witness Depositions

Deponent [Date of Deposition]
Hinoul, Piet - 04.05.2012 Deposition Testimony
Hinoul, Piet - 09.18.2012 Deposition Testimony
Nager, Charles - 06.10.2014 Deposition Testimony
Weisberg, Martin - 05.24.2012 Deposition Testimony
Weisberg, Martin - 08.09.2013 Deposition Testimony
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony

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Other Materials

Other
05.15.2008 Summary of Safety and Effectiveness
2007 Prolift Professional Education Slide Deck
2007 Prolift Surgeon's Resource Monograph
2007 Prolift Surgical Technique Guide
2008 Prolift Patient Brochure
2011 Pelvic Organ Prolapse and Stress Urinary Incontinence Patient Counseling Guide
2012 ABOG - Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 Update of AUA SUI Guidelines- Appendices A11 and A16 (re Complications)
2013 Oct. AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of SUI
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
2014 July - IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI
2015 ACOG, AUGS Practice Bulletin Summary of 155 - Urinary Incontinence in Women (replaces 63 from June 2005)
2015 FDA Consideration about Surgicial Mesh for SUI
2015 Mar EAU Guidelines on Urinary Incontinence
2015 SCENIHR Report, EU Commission FULL - The safety of surgical meshes used in Urogynecological surgery.
52 Slides - Gynecare Prolift Pelvic Floor Repair Systems dated 2007 and 2008
53 Slides - Gynecare Prolift dated 2005 and 2006
6.2.2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair
7/13/2011 FDA Safty Communication: UPDATE on the serious complications associated with transvaginal placement of surgical mesh for Pelvic Organ Prolapse
ABOG and ABU - 2012 Guide to Learning in FPMRS
ACGME Program Requirements for Graduate FPMRS, July 1, 2014.
ACGME Program Requirements.
ACOG - "ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists" {Number 63)
ACOG - "ACOG Technical Bulletin: Urinary Incontinence" (Number 213)
ACOG (2005) Practice Bulletin, Number 63, June 2005. Urinary Incontinence in Women. Obstet Gynecol 2005; 105:1533-45
ACOG (2011) Committee Opinion Number 513. Vaginal placement of synthetic mesh for pelvic organ prolapse. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;188-:1459-1464
ACOG (2011) Frequently Asked Questions. American College of Obstetricians and Gynecologists. ACOG FAQ2
ACOG (2013) Frequently Asked Questions. American College of Obstetricians and Gynecologists. ACOG FAQ183.
ACOG (2015) Practice Bulletin Summary of 155 - Urinary Incontinence in Women (replaces 63 from June 2005)
ACOG (The American College of Obstetricians and Gynecologists) - "Frequently Asked Questions: Surgery for Stress Urinary Incontinence" (FAQ166)
ACOG (The American College of Obstetricians and Gynecologists) - "Frequently Asked Questions: Urinary Incontinence" (FAQ081)
ACOG Practice Bulletin, Number 63, June 2005. Urinary Incontinence in Women. Obstet Gynecol 2005; 105:1533-45

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Other Materials

ACOG, AUGS Practice Bulletin Summary of 155 (replaces 63 from 2005) Urinary Incontinence in Women. November 2015.
AUA – Urinary Incontinence. Updated August 2012
AUA (2011) - Position Statement on the Use of Vaginal Mesh for SUI
AUA (2011) - Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence
AUA (2011) Position Statement on the use of vaginal mesh for the repair of pelvic organ prolapse
AUA (2013) Position Statement on the Use of Vaginal mesh for the Surgical Treatment of Stress Urinary Incontinence
AUA (2013) SUI Patient Guide: 1 in 3 women experience Stress Urinary Incontinence
AUA (American Urologic Association) - "A Patient's Guide - 1 in 3 Women experience Stress Urinary Incontinence"
AUA (American Urological Association) - "A Monograph from the AUA Foundation: Stress Urinary Incontinence"
AUA (American Urological Association) - "AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence"
AUA Foundation (2011) Stress Urinary Incontinence Monograph
AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update
AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009)
AUA National Medical Student Curriculum Urinary Incontinence
AUA National Medical Student Curriculum, updated August 2012
AUA Position Statement on the use of vaginal mesh for the repair of pelvic organ prolapse (Nov. 2011)
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